U.S. FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
MEDICAL DEVICES
ADVISORY COMMITTEE

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MEETING

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TUESDAY,
OCTOBER 11, 2005

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The meeting convened in the Ballroom Salons A and B of the Hilton Washington D.C. North, 620 Perry Parkway, Gaithersburg, Maryland, 20877, at 9:19 a.m., pursuant to notice, Jon B. Suzuki, D.D.S., Ph. D. MBA, Chair, presiding.

COMMITTEE MEMBERS PRESENT:

JON B. SUZUKI, D.D.S., Ph.D., MBA. Chair
MICHAEL E. ADJODHA, MchE Executive
SALOMON AMAR, D.D.S., Ph.D., Voting Member
LEIF K. BAKLAND, D.D.S., Consultant
DAVID L. COCHRAN, D.D.S., Voting Member
B. GAIL DEMKO, D.M.D., Consultant
ELIZABETH S. HOWE, Non-Voting Member, Consumer Rep.
WILLIAM J. O'BRIEN, M.S., Ph.D., Voting Member
DANIEL R. SCHECHTER, J.D., Non-Voting Member, Consumer Rep.
DOMENICK T. ZERO, D.D.S., M.S., Voting Member
JOHN R. ZUNIGA, Ph.D., D.M.D, Voting Member
CHIU S. LIN, Ph.D., FDA

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P-R-O-C-E-E-D-I-N-G-S

9:19 a.m.

CHAIRMAN SUZUKI: Convenes conference.

EXECUTIVE SECRETARY ADJODHA: Thank you, Chairman Suzuki. My name is Michael Adjodha. I'm Executive Secretary of the Dental Products Panel.

Allow me to introduce the members of our panel. Please raise your hand as I call your name.

The Chairman of the Dental Products Panel is Dr. Jon Suzuki. Chairman Suzuki is a periodontist and is a microbiologist, and is Associate Dean of the School of Dentistry at Temple University, Philadelphia, Pennsylvania.

Joining him are the following panel members. Dr. Amar isn't here right now, he's delayed at the airport, I expect him shortly. He's a periodontist and is a Professor at the School of Dental Medicine at Boston University, Boston, Massachusetts.

Dr. David Cochran is a periodontist and is Professor and Chairman at the Health Science Center at

the University of Texas, San Antonio, Texas.

Ms. Elizabeth Howe is a consumer representative, and she is President of Non-Profit Consultants, Auburn, Washington.

Dr. William O'Brien is a materials engineer, and he's a professor at the School of Dentistry at the University of Michigan, Ann Arbor, Michigan.

Mr. Daniel Schechter is our industry representative, and he is General Counsel for Parkell, Incorporated, Farmingdale, New York.

Dr. Domenick Zero is a carriologist and is Professor and Chairman at the School of Dentistry of Indiana University, Indianapolis, Indiana.

Dr. John Zuniga is an oral surgeon and is Professor at the School of Dentistry at the University of North Carolina at Chapel Hill, Chapel Hill, North Carolina.

Joining the panel are the following consultants. Dr. Leif Bakland is an endodontist and is Professor at the School of Dentistry of Loma Linda University, Loma Linda, California.

And, Dr. Gail Demko is a dentist in private practice in Newton Highlands, Massachusetts, who specializes in oral appliances for the treatment of sleep apnea.

Joining us at the table is Dr. Chiu Lin. He is Director of the FDA's Division of Anesthesiology, Infection Control, General Hospital and Dental Devices.

I will now read into the record the conflict of interest statement for this meeting.

FDA is convening today's meeting of the Dental Products Panel of the Medical Devices Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representative, all members and consultants of the panel are special government employees or regular federal employees from other agencies, and are subject to the Federal Conflict of Interest laws and regulations.

The following information on the status of this panel's compliance with the Federal Ethics and Conflict of Interest laws governed by, but not limited

to, those found in Title 18 of the U.S. Code, Section 208, and Title 21 of the U.S. Code, Sections 355(n)(4), is being provided to participants in today's meeting and to the public.

FDA has determined that members and consultants of this panel are in compliance with Federal Ethics and Conflict of Interest laws. Under Title 18 of the U.S. Code, Section 208, Congress has authorized FDA to grant waivers to special government employees of limited financial conflicts when it is determined that the agency's need for a particular individual's service outweighs his or her potential conflict of interest.

Members and consultants of this panel and special government employees in today's meeting have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their employer, spouse, or minor child, related to discussions of today's meeting. These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patent,

patents and royalties, and primary employment.

Today's agenda involves a discussion of general issues related to the classification of several unclassified dental pre-Amendments devices. In accordance with Title 18, U.S. Code, Section 208(b)(3) a waiver has been granted to Dr. Domenick Zero. A copy of the conflict of interest waiver statement may be obtained by submitting a written request to the agency's Freedom of Information office, Room 12A30 at the Parklawn Building in Rockville, Maryland.

Mr. Daniel Schechter is participating as an industry representative, acting on behalf of all industry, related industry, and is employed by Parkell, Incorporated.

We would like to remind members and consultants that if the discussions involve any other products or firms not already on the agenda, for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and the exclusion will be noted for the record.

FDA encourages all participants to advise

the panel of any financial relationships which you have with any firms at issue.

This conflict of interest statement will be available for review at the registration table.

I'd finally like to request everyone in attendance at this meeting take the opportunity to sign the attendance sheet at the front table. Please also turn off your cell phone ringers, so as not to disrupt this meeting.

Thank you.

Chairman Suzuki?

CHAIRMAN SUZUKI: Okay, thank you, Mr. Adjodha.

Before we begin the meeting, we have two informational presentations by the FDA, one on the Critical Path Initiative by Dr. Larry Kessler, and the other on Post-Market Study Design by Dr. Tom Gross.

Is Dr. Kessler present?

Okay, is Dr. Gross here?

DR. GROSS: Okay, good morning. I'm Tom Gross, I'm the Director of the Division of Post-Market Surveillance, and I'd like to take a few minutes of

your time today to talk about recent changes in our condition of approval study program.

Before I do that, I'd like to talk to you a little bit about our office, that is the Office of Surveillance and Biometrics, which is now responsible for the condition of Approval Study Program.

Now, there's some basic functions that our office serves for the Center. First and foremost, we provide support for pre-market review. We have about 50 statisticians who provide support for all statistical aspects of pre-market submissions. We have about a dozen epidemiologists who are involved with PMA reviews and helping to design and conduct condition of approval studies.

Our office is also responsible for detecting signals of potential public health problems through our nationwide passive adverse event reporting systems, namely, our mandatory system, the medical device or MDR reporting system, and our MedSun system, the medical device safety network, which is comprised of 350 healthcare institutions throughout the United States who report on clinical events in their

institutions.

We are also responsible for characterizing the risk of potential public health problems. Our epidemiologists are in charge of this, and they use a variety of tools from literature reviews to conducting and designing de novo studies.

We are also responsible for coordinating center responses on actions regarding these potential public health issues. We convene expert panels within the Center to deliberate these issues and offer recommendations to Center senior management.

And lastly, we are responsible for interpreting our medical device reporting regulation, what needs to be reported and violations of that regulation.

Now, let's move on to condition of approval studies. As you all know, these studies are ordered as a condition of approval for PMA devices. Our regulations clearly stipulate that these post-approval requirements can include the continuing evaluation and periodic reporting on the safety, effectiveness and reliability of the devices for its

intended use. This regulation gives us our broad authority in mandating these condition of approval studies.

Now in 2002, our Center took a look at how well we were doing with these studies. To that end, we looked at PMAs that were approved from 1998 through the year 2000. All tolled, there were 127 PMAs that were approved, and about a third of those had clinical condition of approval study orders.

The bottom line of our evaluation was the following, that CDRH had limited procedures for tracking study progress or results, that our IT and other systems were very deficient in this regard. There's large turnover of lead reviewers that resulted in lack of follow-up. Approximately, 40 percent of those reviewers who were assigned to the PMA at the time of submission were no longer associated with that PMA at the time of this study in 2002. And lastly, there were lack of pre-market resources. Those resources were appropriately devoted to pre-market reviews and pre-market submissions, leaving little left over for post-market oversight.

Now, based on these study results, and based on a pilot that we had underway in which epidemiologists were part of the PMA review teams, we developed a strategy for change, and the goals for that change were very simple, which was to obtain useful and quality post-market information as the device enters the market, to obtain real-world use data, to better characterize the risk and benefit profile of these devices, for instance, their long-term performance, and lastly, to add to our ability to make sound scientific decisions based on timely and quality information.

Now, what did we do in terms of this change? We transferred the condition of approval study program from the pre-market side to the post-market side, from the Office of Device Evaluation to our office, the Office of Surveillance and Biometrics. We did so because we had the resources and the expertise to handle these studies. We developed and instituted an automated tracking system for these studies that were instituted this year in April, to acknowledge the receipt of study protocols and interim

reports, and to follow-up when reports were not received.

As a result of the success of our pilot, we now have epidemiologists who are part of all PMA review teams, and their functions are the following. They are tasked with the development of post-market monitoring plans during pre-market review, how to best monitor these products for safety issues in the post-market period. They take the lead in developing well-formulated post-market questions, leading in the design of these studies, leading in the evaluation of the study progress and results after approval, and they continue to work with the PMA throughout -- with the PMA team throughout this process.

We also address the motivation for better study conduct. How can the agency, as well as industry, do a better job in the conduct of these studies? First and foremost, we have to agree as to what important post-market questions need to be addressed, and then to design adequate and quality study protocols to address those questions. We need to acknowledge the receipt of the protocols and the

interim reports, as I previously noted, and to provide feedback on the studies in real time.

For the agency to be more transparent we are planning on posting the study status of these condition of approval studies on an agency website, and lastly, we do have the authority to mandate post-market studies under other authorities if these are not adequately done under our condition of approval authority.

Lastly, what's the impact on the Advisory Panel? During the approval process, we will attempt to lay out the important post-approval public health questions, and the possible approaches for panel consideration. And then, during the post-market period, FDA or industry will update the panel on the progress and results of these studies.

That concludes my remarks. Thank you very much.

CHAIRMAN SUZUKI: We can now call on Doctor Kessler.

DR. KESSLER: Good morning. I'm not Sousan Altaie, as you can see from the slides up there. I'm

giving the presentation in her stead. My name is Larry Kessler, I'm the Director of the Office of Science and Engineering Laboratories. Most of you probably don't know about the Office of Science and Engineering Laboratories. If you have a question about us, we'll spend a few minutes afterward, but today I'm here to talk to you in Sousan's stead about the Critical Path Initiative in Medical Devices, part of the Critical Path Initiative for the entire Food and Drug Administration started by then Commissioner Mark McClellan as couple of years ago.

So today, in about the next ten to 15 minutes, I'm going to talk to you about our Critical Path Initiative, what it is, why we are interested, what are the critical path tools, and the medical device areas of specific interest to us, and hopefully to you, what are medical device critical path projects, we have a few ongoing and I'll talk about a couple of them, and then ways in which you, the panel members, can get involved in the Critical Path Initiative.

What the FDA's Critical Path Initiative

is, is a serious attempt to make product development more predictable and less costly. I want to focus for a second on both of those, because one of the problems that we have heard over and over from our industry is that the difficulty that they have in planning or working with the FDA has to do with predictability. When we don't know the right questions to ask, or when we go back and forth with a company about trying to figure out how to put something on the market, it makes it harder for them to do their job, harder for us to do our job, and everyone would like less costly review process, as well as what we can do to get things on the market more efficiently.

This fairly simple diagram is a rather easy way to understand what we view as where we fit in in the critical path process from very basic research and prototype design or discovery through actually getting a product on the market. Some time after clinical development, and in between market application and approval, trying to figure out how to get the product on the market involves the Food and Drug Administration.

Prior to that, from the very part of the design or discovery through getting things through FDA, we consider that the critical path. A lot of the work done there by industry are in lab studies, pre-clinical animal studies, bench studies, as well as clinical trials. The degree to which we can improve what's predictable in that period, and the kind of science and applied science that can be done to effectively get products on the market, we think will help the industry and help patients ultimately.

Some people might ask, why isn't this the job, not only of industry, but also sometimes of the National Institutes of Health? While they are valuable partners, they tend to leave themselves way back on the left-hand side of that diagram, so the bulk of NIH research you'll find in the basic research arena, maybe sometimes in design or discovery, and for devices rarely, but occasionally, in clinical procedures and clinical trials.

Why are we interested? Well, I'm going to digress from Sousan's slide for just a minute, and try and give you a little bit of background. The big

initiative for the entire agency's Critical Path process began with the clear recognition of things, not in the device arena, but in the drug and biologic arena. The pipeline in drugs and biologics has been shrinking over the past five years dramatically. The number of new molecular entities approved, the number of new drugs coming to market, has shrunk dramatically. Some of the concern at the agency level was related to what they thought was difficulties getting products through to market, and Dr. McClellan, and after him both Dr. Woodcock and Dr. Crawford, thought it was important to try and focus on scientific and technical issues that were inhibiting products from getting to market, and the early focus was drugs, and not devices, principally because the device industry has remained relatively healthy over the past decade, and the amount of turnover that we see in terms of new products has not abated.

Nevertheless, we felt there still were significant things that FDA could do, working with our academic colleagues, our clinical colleagues, and our industry partners, to improve the process via putting

some attention in what we considered the critical path for device development.

So, we remain interested from the Center for Device and Radiological Health because of significant benefit of bringing innovative products to the public faster, because of our unique perspective on product development. One of the things that most people don't recognize is that we not only see the successes of products, we see the failures. An individual company will certainly see its own successes and failures, they will not often have a wide perspective on a product type across many companies.

In addition, our involvement in the Critical Path Initiative will help us develop guidance and standards that foster innovation and improve the chances of success of products getting through our system. While we have an extraordinarily high approval rate, there still are a number of cases where we think things can be improved.

So, we want to work together, as I've said, with industry, academia and patient care

advocates, and we are trying to modernize, develop and disseminate solutions or tools, applied technology tools, applied research tools, that will address scientific hurdles that will impact an industry-wide product development.

We are focused on three areas, an assessment of safety, and I suspect this is a good thing that follows Tom Gross' presentation, if he remained in the audience, how to predict if a potential product will be harmful. So, we are looking at a variety of techniques, not only mining the currently available post-market experience data we have, but also trying to develop computer simulation models and other tools and techniques that could help predict safety issues.

We are also looking to see if we can improve tools that will determine the potential product will have medical benefit, and this, indeed, can be a challenge because the sine qua non of our evidence-based system these days is a randomized trial, trying to figure out how randomized trials can be supplanted by other tools and techniques is always

a challenge in the device area, particularly hard because there are trials that cannot be done sometimes, but trying to prove efficacy always proves a little bit challenging.

And finally, and this is something that you may have a sense of, if you've looked at the unfortunate headlines over the past year, and week in and week out look at the FDA and seen our recalls, seem to be rather exciting sadly, manufacturing products can be a challenge, very difficult. We have a really interesting example. I won't mention the specific product, you can probably guess what it is, launch for this product was about a year and a half ago, it was one of the most exciting products in the medical device development. And, interestingly enough, in one of the very unusual cases the Center for Medicare and Medicaid Services approved reimbursement for this exciting product months before we approved it. And, the months of delay had nothing to do with the panel or the clinical trials, it all had to do with getting this major national company up to speed in manufacturing a reliable product under the

quality system requirements. And, this is a major international company, with a major blockbuster product that was withheld from market for months, months and months. And, even reimbursement was settled, which is almost never the case, and this was about a year and a half ago, so I'll leave it to you to guess. I don't want to mention the company, because it may suggest that they are not -- they didn't do a good job. It's hard to manufacture a complicated medical device and do so under the quality system requirements.

So, these are three areas, assessment of safety, proof of efficacy, industrialization, where we think applied research tools and working together with industry, academic, our clinical colleagues and patient advocates, could prove beneficial.

And, examples of those tools are as follows. I mentioned computer simulations, the middle of the slide, biomarkers, and what we are trying to do in enhancing our understanding of the way in which biomarkers work is another example. As Tom probably told you toward the end of the slide, trying to figure

out how we can improve post-market reporting, improve our feedback process, and speed up the intergenerational time of the device pathway, and there are a number of opportunities that I'll talk about real briefly.

I just want to remind you that while a lot of this initiative did start with the drugs, and we use drugs a lot as a stalking horse sometimes, devices are very different. They aren't simple molecules, there tend to be complex components, and the other thing I want to point to which turned out to be really critical in understanding how devices work is about three quarters of the way down the right side, what we call use error, I apologize it says user error, we are trying to get away from that terminology and use the sense of use error. Devices, unlike drugs, almost always have, not only the patient and the product itself, but a clinician involved, often a doctor or a nurse, and an environment, and those four things contribute to device problems that we don't see at the same level in the drug world. So, understanding how use errors occur can be critical, and our trying to

understand them, and industry trying to understand them to prevent them, is the kind of thing we are looking at in the Critical Path.

Device safety tools, we are developing a biocompatibility database, which could be very efficacious if we can make it public, so that companies can speed their products to market, and review what's in the database, and avoid using certain products that would be in-biocompatible with the human body. We are looking at effective products on disease or injured tissues. In my laboratories, we have at least three different models of damaged organs or ill animal models that can be used to test products against. When you test products against healthy animals you get certain kinds of results, you test the same ones against sick or diseased animals or their organs, and you may get different answers, and because products in the medical arena are used most often with disease patients, animal models of compromised health can be valuable to assessing safety issues.

For effectiveness tools, we've been talking with a number of companies about using

surrogate endpoints for cardiovascular clinical trials, and one of our colleagues, Charles Taylor in Stanford, is doing some computer simulation modeling and collaborating with us for implanted devices.

In mass manufacture industrialization, I think it's an area that's been very long neglected, and we only have fledgling work in this area, and we'd really be excited about more concerted effort in industrialization, trying to develop practice guidelines for follow-up of implanted devices, and look at validated training tools for devices with a known learning curve. As I said, a lot of devices run into problems in the clinical or community setting, because of the user and the environment, and we are trying to improve how we get people up to speed on known devices, or devices with a known learning curve.

So, in specific projects, our validation of biomarkers, we are trying to put together a blood panel to assess sensitivity and specificity, for peripheral vascular stints, computer models of human physiology to test and predict failure, and finally, we are trying to work with the obstetrics community to

develop a clear path in intrapartum fetal diagnostic devices, and this would principally be a guidance type effort.

Here are a few others, you can read them, and I can certainly -- I think you already have somewhere in your package these kind of issues, and we can talk about them at some length if you'd like.

I want to point out the last one, the neural tissue contracting materials, extensive neurotoxicity testing, we are doing some of the work on that, neurolaboratories as well.

If you are interested, what are we doing? Well, we are continuing to review comments that were sent last year to the docket. We are trying to figure out which areas would most benefit from research in the development of Critical Path evaluative tools. Any suggestions you have would be most welcome. Please direct them directly to Dr. Sousan Altaie, her name is on the first slide here, and you can find her in our global directory. I'm sure if you need to we can provide you her e-mail address, so if you have any comments or suggestions in the product areas that you

are involved in, please feel free to contact Sousan directly.

We are compiling a National Path Critical Opportunities List and publish it. While the resources of FDA are better than they ever have been under the Medical Device User Fee and Modernization Act, we are still an extremely leanly funded agency. I can tell you our laboratory budget, if any of you is interested at some point, I'll tell you off line, and it's kind of embarrassing when you think about comparing it to real science effort. So, we really need to partner with academic, other government agencies which we try to do as often as we possibly can, and the clinical community, to get these Critical Path tools developed.

Here's a web address for you. It's in your packet I'm sure, and the docket is always open for suggestions and comments. We review that on a routine basis, and there's a web page providing links to the Critical Path White Paper which describes the original background for this project. We hope that you'll become engaged, and if you have any questions

or comments you can ask me now or you can ask Sousan in the future.

I want to thank you for your time and attention. I hope I haven't overstayed my welcome.

Thanks.

CHAIRMAN SUZUKI: Thank you, Dr. Kessler, and thank you, Dr. Gross.

We will now proceed with the meeting. I note for the record that voting members present constitute a quorum for the meeting, as required by 21 CFR, Part 14. We will now proceed with the agenda.

The first item on our agenda is the open public hearing, the first of two open public hearing sessions for this meeting. A second open public hearing will be held tomorrow. At these times, public attendees are given the opportunity to address the panel to present data or views relevant to the panel's activities.

Please note that there will be opportunities during the classification discussions to comment on the proposals for each device.

Both the Food and Drug Administration and

the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the Advisory Committee meeting, the FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting.

Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have a financial relationship. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

I would like to remind public observers at

this meeting that while this portion of the meeting is open to public observation, public attendees may not participate except at the specific request of the Chair. You will be given no more than ten minutes for your presentation.

No individual has given advanced notice of wishing to address this panel. If there is anyone now wishing to address the panel, please identify yourselves at this time.

I would like to ask that persons addressing the panel come forward at this time, identify yourself, speak clearly as the transcriptionist is dependent on this means for providing an accurate transcription of the proceedings of this meeting. If you have a hard copy of your talk available, please provide it to the Executive Secretary for use by the transcriptionist to help provide an accurate record of the proceedings.

Seeing no one, I'd like to turn the program over to Dr. Runner.

DR. RUNNER: Good morning. I'd like to welcome members of the Dental Product Panel, our

consultants, FDA staff, and all of our stakeholders in the audience, to this meeting of the Dental Products Panel. My name is Susan Runner, and I'm the Branch Chief of Dental Devices, in the Division of Anesthesiology, Infection Control, General Hospital, and Dental Devices, of the Office of Device Evaluation, of the Center for Devices and Radiological Health, of the FDA. That's a long introduction, isn't it?

Over the next two days, you are going to asked for your recommendation on the classification of seven dental devices that we believe have been on the market since prior to the initiation of the Medical Device Amendments of May 28, 1976, and they have never been classified by previous panels.

During the next two days, you'll get to hear from every single one of my branch members, beginning with Ms. Myra E. Browne, a biologist, and she will be giving a presentation on Artificial Saliva. Then, Dr. Robert Betz on Retraction Cord. Then, Ms. Angela Blackwell, biomedical engineer in my branch, on Oral Wound Dressings. Dental Electrical

Anesthesia, by Mr. Andrew Steen, who is a mechanical engineer. Ms. Myra Browne again on Root Canal Cleansers. Mr. Michael Ryan, who is a biomedical engineer, on Root Apex Locators, and finally, Dr. Kevin Mulry, on the Dental Mouth Guard.

Secondly, we will be looking at a general issue, and we will ask for your input on the OTC use of dental mouth guards, and that will be presented tomorrow by Dr. Kevin Mulry.

We appreciate your time and welcome your expertise, and we hope to have a very good meeting. I think we'll not have the break as per schedule, but we'll start right out with Ms. Browne's presentation.

CHAIRMAN SUZUKI: Next on our agenda is FDA's presentation on the Proposed Classification of Artificial Saliva, Ms. Myra Browne.

MS. BROWNE: And, I'd like to thank the panel for coming this morning. This morning we will be seeking the panel's recommendation to classify artificial saliva. I will be presenting the proposed classification of artificial saliva devices. This presentation includes device identification,

classification issues, and health risk aspects of the device.

This slide outlines the topics I intend to go through during my presentation. This includes a description of artificial saliva, a regulatory history of artificial saliva, any medical device adverse events submitted, the risk to health associated with artificial saliva, and FDA's classification proposal for artificial saliva.

Artificial saliva is intended for the temporary relief of xerostomia, which may result from an illness, chemotherapy, radiation, stress or aging. It is used to physically replace moisture and lubricate the mouth.

These devices are typically composed of carboxymethylcellulose, salt, buffers and other additives. These devices are commonly marketed as sprays, gels and lozenges, and they are available either by prescription use or over the counter.

These products are used to mimic natural saliva, but do not stimulate saliva production. These devices are considered as replacement therapy, rather

than a cure. Artificial saliva devices do not include products intended to alter salivary flow or to treat mucositis by chemical or metabolic means. Such products would be considered drugs.

The only pre-amendment device identified as having been marketed prior to 1976 is Xero-Lube manufactured by Scherer, Incorporated. Artificial saliva devices are currently regulated via the pre-market notification 510(k) process. To date, FDA has cleared 15 artificial saliva 510(k) to date. There have been no medical device reports through FDA's adverse event reporting system for artificial saliva devices to date.

This table identifies the risk to health associated with artificial saliva and FDA's proposed controls to address these issues. The risk to health associated with artificial saliva are improper use and adverse tissue reaction. Mitigation measures would include labeling recommendation, full chemical characterization, and biocompatibility testing. Chemical characterization is a critical component of risk mitigation. The inclusion of chemical entities

with adverse chemical and/or pharmacological properties may pose a serious risk to health.

To conclude, FDA is proposing the following classification for artificial saliva devices. The identification would read, an artificial saliva device is intended for the relief of xerostomia. The classification would read, Class II, Special Controls. The special control for this device would be the guidance document, Class II, Special Controls Guidance Document, Artificial Saliva.

Thank you.

CHAIRMAN SUZUKI: I would now like to ask the panel if it has any questions on the presentation.

Hearing none, we now have an open comment session regarding the proposed classification of artificial saliva. I'd like to ask if there's anyone in attendance who wishes to address the panel, and if there are please approach the microphone and identify yourself for the record.

Okay, there are none.

Ms. Shulman will now lead the panel to complete the classification forms.

DR. COCHRAN: Jon?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: This is David Cochran. I have a question.

The chemical characterization of the material is something used to mitigate the risk. Is that not included if it's a Class I device?

CHAIRMAN SUZUKI: I'll ask Ms. Browne to respond to the question.

MS. BROWNE: If it's a Class I device, and we might not -- well, we would see it, but the risk -- I'm trying to think, if it were Class I --

DR. RUNNER: If it were a Class I device, it would be most likely exempt, and, therefore, we would not see the chemical characterization of the device, because that would not be something that would come in as a 510(k).

MS. BROWNE: The exemption would be tripped unless it were a new product with a totally different -- not as a composition already on the market, we would not see that device. And, we feel that the risk, it should be in Class II.

DR. COCHRAN: But, if there was a different composition it would be tripped. So you would see it.

MS. BROWNE: We would see, it, yes, we would see the composition of it.

DR. COCHRAN: So, I guess the question is, is the chemical composition of the one that's available in 1976, is that a safe product at this point?

MS. BROWNE: Yes. Well, we feel it's a safe product, but over the years they have evolved where the composition has changed and the devices work, the mode of actions are slightly different, that we feel that the Class II would be substantiated.

CHAIRMAN SUZUKI: Did that answer your question, Dr. Cochran?

DR. COCHRAN: Yes.

CHAIRMAN SUZUKI: Thank you.

Any other questions?

Yes, Dr. Zero?

DR. ZERO: Is there -- some of these products may contain some fluoride, is that correct?

MS. BROWNE: As of now, I don't believe

we've had any with fluoride, but we would -- they could contain fluoride. They also might be -- well, fluoride isn't considered a drug, but we do have several devices that do contain fluoride. However, no one is allowed to make a claim for the fluoride content in the device.

So, therefore, if it did contain fluoride, I would ask them what the purpose of the fluoride is, but I would not let them make any claim to it. So, if fluoride were an active ingredient, I believe it would be regulated as a drug, or at least a consult from drug.

DR. ZERO: So, if it had fluoride, would there be a limit on the level of fluoride? Say, it's 1 ppm, or 10 ppm, or 100 ppm.

MS. BROWNE: Yes, I would ask Drugs, I would not make that call myself, I would ask the Center for Drugs.

DR. ZERO: So, there's a threshold when if it was high enough it would then be considered as a drug?

MS. BROWNE: I'm not sure, would it be?

DR. RUNNER: Typically, we have products that have fluoride in them. However, they haven't been allowed to make claims. If they want specific claims for the fluoride, then we would consult with Drugs. For example, if they wanted anti-caries claims, et cetera, they would need a drug consult since the fluoride is considered a drug.

Limits, we've looked at the limits that have been typically in some of the products, like restorative materials, without a drug consult, and we actually ask for release data on those with fluoride in them.

DR. ZERO: Okay. And, typically, the level of fluoride is in the ppm range, low, like 1, 10?

DR. RUNNER: Low-dose, yes.

DR. ZERO: Okay, thank you.

CHAIRMAN SUZUKI: Any other questions?

Yes, Ms. Howe?

MS. HOWE: I'd like to just clarify, if the intent for this product is the same, then if a manufacturer changes ingredients what does that trip? Does that trip a 510(k), a reconsideration, is it

just a change of intent that trips something?

MS. BROWNE: Yes, it would still be a 510(k), unless it were -- as long as the intended use were the same, but it had a different ingredient, it would still be the same classification, it would just need a new 510(k). But, if it's in Class II, it will always -- you will see all of that.

CHAIRMAN SUZUKI: Okay, thank you.

Dr. Demko?

DR. DEMKO: I'm just asking a question, in that I know that some of them that are on the market now are actually oil-based, rather than carboxymethylcellulose, and I have tremendous concerns about those, vis-á-vis the CPAP, which dries your mouth, so is that something that I bring up for discussion now, or do I just write it in my notes, in my review?

MS. BROWNE: No, you should -- you might want to discuss it now, because we have seen those products.

DR. DEMKO: Okay, because one of the things that came up, there are two types of positive

air pressure for treating obstructive sleep apnea, where they are using air pressure to inflate the airway, that they are oral delivery. They are either with an OPAP or an Oracle device, where the air is delivered into the mouth, and the patients who use this type of oral delivery for CPAP complain horrendously about dry mouth, even with use of humidifiers on their CPAP machines.

And, the question has come up in the past, there would be some dentists who would tell patients to use a fine mist of canola oil or a fine mist of olive oil, because that way it doesn't evaporate and it protects the mucosa from the drying effects of the CPAP.

The catch is, the pulmonary docs went nuts, because there is a certain type of oil embolus pneumonia that patients can get if you actually blow this oil into the lungs. So, I would want to see this looked at by a pulmonary physician, as to what their concerns would be with use of a CPAP.

MS. BROWNE: Well, is the oil, is the mist, is it actually, you know, labeled as an artificial

saliva device, or are they just taking oil and spraying it down their throat?

DR. DEMKO: When it started out with the OPAP back about eight years ago, they were just being told to use oil. So, but knowing that patients tend to treat themselves, and they are going to try and find an artificial saliva that's going to make their mucosa more comfortable with oral delivery, say if they have chronic nasal congestion, that whether that be labeled out saying, do not use this if you are using CPAP, because I'm not sure how much of what is instilled into the mouth actually gets into the airway.

MS. BROWNE: Okay, well, that's another reason that you need to keep it into Class II, otherwise, if one has it on the market, and you put it in Class I, the next one with the identical formulation I won't have any control over the labeling.

So, if you don't put it in Class II, I won't have any control over the labeling at all, and I don't believe I've seen labeling for the specifics of

what you were talking about.

CHAIRMAN SUZUKI: Did that answer your question, Dr. Demko?

DR. DEMKO: Yes.

CHAIRMAN SUZUKI: Any other questions from the panel?

Okay, thank you, Ms. Browne.

Ms. Shulman?

MS. SHULMAN: Good morning. Again, each panel member will fill out their own form, the panel chair will take the vote after we go through each question.

So, on the top of the form the panel member and the date, and the generic type of device. We'll go through the very first question, is the device life-sustaining or life-supporting? I don't know if you want to just go around and take a vote, however you'd like to do it.

CHAIRMAN SUZUKI: I'll ask the voting members in order, and I'll begin with Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: And, Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: And, the Chair votes no.

And, the non-voting members would like to comment, Ms. Elizabeth Howe?

MS. HOWE: I would say no.

CHAIRMAN SUZUKI: And, Mr. Daniel Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Okay.

MS. BROWNE: Thank you.

Question number two, is the device for use which is of substantial important in preventing impairment of human health?

Again, if you'd like to go around.

CHAIRMAN SUZUKI: Yeah, I'll go around.

Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Doctor Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: And, I neglected the consultants on that last table of questions.

Dr. Bakland? So, you can answer twice, the previous question and this question.

DR. BAKLAND: No to both.

CHAIRMAN SUZUKI: And, Dr. Demko?

DR. DEMKO: No to both.

CHAIRMAN SUZUKI: And then, our non-voting consumer and industry representatives for their opinions.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: And, Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Okay.

MS. BROWNE: Okay, thank you.

Question number three, does the device

present a potential unreasonable risk of illness or injury?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Doctor Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Non-voting members.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: And, I would say no, except with the oils and question talking to a pulmonary specialist.

CHAIRMAN SUZUKI: Okay.

And, the Chair votes no.

MS. BROWNE: Thank you.

Number four, did you answer yes to any of the above three questions? The answer to that is no, so we go to question five.

Is there sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness? Remember the general controls are the Class I controls.

CHAIRMAN SUZUKI: Okay.

Dr. Cochran?

DR. COCHRAN: The answer is no.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: The Chair votes no.

The consumer and industry reps.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: And, the consultants for their opinions.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: And, Dr. Demko?

DR. DEMKO: No.

MS. BROWNE: Okay, thank you.

Then if no, we go to question six. Is there sufficient information to establish special controls in addition to the general controls, to provide reasonable assurance of safety and effectiveness? The special controls are the Class II controls.

CHAIRMAN SUZUKI: Okay.

Dr. Cochran?

DR. COCHRAN: Yes.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: The Chair votes yes.

Ms. Howe?

MS. HOWE: Yes.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Yes.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Yes.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Yes.

MS. BROWNE: Okay, thank you.

If yes, classify in Class II, and we move on to Item seven. Item seven, if there is sufficient information to establish the special controls to provide reasonable assurance of safety and effectiveness, identify below the special controls needed to provide such reasonable assurance for Class II. And, what Ms. Browne talked about was the guidance

document with the first one, but you can also recommend anything else listed or any other that you would like to list as a special control.

CHAIRMAN SUZUKI: Okay.

So, Ms. Browne indicated primarily the guidance document.

DR. COCHRAN: I have a question.

CHAIRMAN SUZUKI: Okay, Dr. Cochran has a question.

DR. COCHRAN: The question, could you go over again what testing guidelines is?

MS. BROWNE: That would be testing guidelines will be included usually in the guidance document, what kind of test we are looking for, or what kind of results we are looking for, anything like that.

DR. COCHRAN: So, that's included in a guidance document?

MS. BROWNE: Most of the time if testing is required to determine substantial equivalence, that will be included in the guidance document.

CHAIRMAN SUZUKI: Okay, are we ready to

vote?

Dr. Cochran?

DR. COCHRAN: Guidance document checked on number seven.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: Guidance document.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Guidance document.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Guidance document.

CHAIRMAN SUZUKI: And, I report the same, guidance document.

The consumer and industry representatives.

Ms. Howe?

MS. HOWE: Guidance document.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Guidance document.

CHAIRMAN SUZUKI: And, the consultants for their opinions.

Dr. Bakland?

DR. BAKLAND: Guidance document.

CHAIRMAN SUZUKI: And, Dr. Demko?

DR. DEMKO: Guidance document.

MS. BROWNE: Okay, thank you.

Questions eight and nine we can skip, because it only has to do with performance standards, and performance standard is not one of the special controls chosen.

Question ten we can skip, because that only has to do if there it was recommended to go into Class III.

Question 11, this is also for your current thoughts, but this was a pre-amendment prescription device, so we are identifying the needed restrictions. The first one is a prescription statement, only upon the written or oral authorization of a practitioner licensed by law to administer the device, or you can add onto that, for use only by persons with specific training or experience in its use, or only in use in certain facilities.

CHAIRMAN SUZUKI: Okay, are there any questions before we proceed with the vote?

Mr. Schechter?

MR. SCHECHTER: Yes. I believe that it was mentioned that there are currently prescription and over-the-counter devices in this category.

MS. BROWNE: They did.

MR. SCHECHTER: So, I assume that would be the intention to continue that way?

MS. BROWNE: That's fine.

MR. SCHECHTER: Okay.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes, I had a similar question. There are over-the-counter products available. Is there an option in 11 for over-the-counter items, because they seem to indicate that they would be prescription items, because it says, written or oral authorization.

MS. SHULMAN: Right. Under the other you can write down also over the counter, so it wouldn't be a needed restriction, but we would have the comments that it could either be prescription or over the counter.

DR. O'BRIEN: Okay.

CHAIRMAN SUZUKI: Okay, was that clear?

DR. COCHRAN: So, was that the first box and the last box?

MS. SHULMAN: The first box and the last box you can write the other for the over the counter.

CHAIRMAN SUZUKI: So, by the first box that would include the OTC and the prescription?

MS. SHULMAN: Right, for the other we are going to say that it's also available over the counter. This is one of the kind of weird situations where it's both prescription and over the counter.

CHAIRMAN SUZUKI: It's both, okay.

Are we ready to proceed with the votes?

Dr. Zero?

DR. ZERO: Is there a specific need to maintain the prescription status in this product classification?

MS. SHULMAN: I'll let the experts answer.

MS. BROWNE: The ones that I have that are on the market originally were OTC, but companies actually made a request for some of these to be sold by prescription use, and one company has both uses.

So, they've asked for both, and we allow

them to do it simultaneously, we give approval to both ways.

DR. ZERO: But again, the question was, is there a need for --

MS. BROWNE: For a prescription?

DR. ZERO: From a regulatory point of view.

MS. BROWNE: No, but if a company wants to do it by prescription that's their prerogative.

DR. ZERO: Thank you.

DR. ZUNIGA: I have a question.

CHAIRMAN SUZUKI: Okay, Dr. Zuniga speaking.

DR. ZUNIGA: Along the same line, would that allow the company that currently is this approval on, and that company that currently allows or requires a prescription, to then go to OTC?

MS. BROWNE: They can have it simultaneously. It doesn't matter. They can be both at the same time . We allow that, and actually we have one artificial saliva product on the market that did ask for both at the same time.

CHAIRMAN SUZUKI: Okay, other comments or

questions?

If not, we'll proceed with a vote, beginning with Dr. Cochran.

DR. COCHRAN: I'd vote to check both the first and last box.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: First and last box, and the comment also, over the counter.

CHAIRMAN SUZUKI: And, can you specify the comment under other?

DR. O'BRIEN: Under other, yes.

CHAIRMAN SUZUKI: And, under the comments, maybe Dr. Cochran would like to respond?

DR. COCHRAN: Yes, I would include over the counter.

CHAIRMAN SUZUKI: OTC.

Okay, do you agree, Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Okay.

Dr. Zero?

DR. ZERO: The first and last box, with the

specific comment also, over the counter.

CHAIRMAN SUZUKI: Okay.

Dr. Zuniga?

DR. ZUNIGA: The first and last box, with the specific comment under other, allow over the counter.

CHAIRMAN SUZUKI: I respond first and last box, to including OTC for other.

The consumer and industry representatives.

Ms. Howe?

MS. HOWE: The first box and the description in over that it's over the counter.

CHAIRMAN SUZUKI: Okay.

Mr. Schechter?

MR. SCHECHTER: By prescription and other available OTC.

CHAIRMAN SUZUKI: Okay.

And, our consultants.

Dr. Bakland?

DR. BAKLAND: The first box, and the fourth box, other, OTC.

CHAIRMAN SUZUKI: Okay.

And, Dr. Demko?

DR. DEMKO: The first box and the last box, with the comment of allowing over-the-counter use.

MS. SHULMAN: Okay, thank you.

If we could move on to the supplemental data sheet. Again, question one, the generic type of device.

Question two, the Advisory Panel, Dental.

EXECUTIVE SECRETARY ADJODHA: Margie, can you specify what they mean by generic type of device?

MS. SHULMAN: Just the artificial saliva, that's generic.

DR. ZERO: And, you want Advisory Panel member as opposed to --

MS. SHULMAN: We would like your names on the sheets also, so you can put Dental and then your name, please.

And, question three we can fill out, is this device an implant, yes or no.

Question four, the indications for use in the device labeling, we can say, as presented, or you can comment on the indication for use that was

presented by Ms. Browne. Do you need a full back-up or anything?

So, if you want you can go around and discuss if there's any changes or any comments you'd like to make to that, or just as presented.

CHAIRMAN SUZUKI: This really designates the prescription, correct?

MS. SHULMAN: The prescription, no, no, that's just the identification of the device and the classification into Class II, but it does not address prescription or over the counter.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: If everyone agrees, is there anyone who does not agree to that? Are there any comments?

Okay, thank you.

Then the identification of the risks to health presented by the device.

EXECUTIVE SECRETARY ADJODHA: Margie, are we going to vote on that one?

CHAIRMAN SUZUKI: Do we necessarily have to vote on each?

MS. SHULMAN: No, at the end we can vote on the sheet.

CHAIRMAN SUZUKI: Okay.

The identifications of the risks that were presented, was there any comments or additions to any of those? Do you want to back up?

CHAIRMAN SUZUKI: Would anyone like to comment, were there any additional risks?

DR. ZERO: Mr. Chairman?

Dr. Zero?

DR. ZERO: Based on the comment made about the lipids, do we need to have any specific additional wording?

MS. SHULMAN: You can certainly write that down, that is another concern. That could be addressed maybe in the labeling.

DR. O'BRIEN: Now, in filling out the form, do we put the identified risks as given?

MS. SHULMAN: You do not need -- yes, you can say, as presented in the Panel meeting, you do not have to rewrite those.

DR. O'BRIEN: Okay.

MS. SHULMAN: Okay.

The next question is the classification which was recommended in the Class II, then you will vote on the priority for high, medium or low, and then as to how fast or quickly you would like us to go back and write the proposed rule and the final classification. It's usually a high, medium or low. There are no time frames associated with the high, medium or low. So, if you just want to go around and let us know if you consider it high, medium or low.

CHAIRMAN SUZUKI: Would you like us to go around regarding classification also, or just high, medium or low?

MS. SHULMAN: Just high, medium or low.

CHAIRMAN SUZUKI: Okay.

I'll begin with Dr. Cochran again.

DR. COCHRAN: Low.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: Low.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Low.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Low.

CHAIRMAN SUZUKI: The Chair also indicates low.

Ms. Howe?

MS. HOWE: My interpretation would be high, and my justification for that is, even though it's out there on the market, and maybe for that reason it should be low, I guess I'm thinking in terms of if there are manufacturers out there who want this information so they can go ahead and get more products on the market, this is something that several consumers use in terms of people who are receiving chemotherapy, whatever. That's how I would interpret it, that we want people to know that this is a product that we really want to have out there as classified and available.

CHAIRMAN SUZUKI: Okay, thank you, Ms. Howe.

Mr. Schechter?

MR. SCHECHTER: Low.

CHAIRMAN SUZUKI: Okay.

The consultants.

Dr. Bakland?

DR. BAKLAND: Low.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Low.

MS. SHULMAN: Okay, thank you. So, that will be low.

The question seven, we may skip because it's not an implant, or life sustaining, or life supporting, that was voted on on the first sheet.

Number eight, the summary of information, including clinical experience with judgment upon which the classification recommendation was based. You may also say the information as presented in the Panel meeting, or, of course, add anything else you wanted to say.

Question 11, is any other needed restrictions besides the prescription use statement or it can be over the counter, are there any other needed restrictions on the device as known? If not, you may say none, or any comments.

CHAIRMAN SUZUKI: Any comments? Any

questions?

Okay, none for number nine.

MS. SHULMAN: On the next sheet, we may skip question ten, because that only has to do with Class I devices.

Question 11, if the device is recommended for Class II, recommend whether FDA should exempt it from pre-market notification. We need to vote on that.

CHAIRMAN SUZUKI: Okay. Any questions first before we vote?

Okay, I'll ask Dr. Cochran.

DR. COCHRAN: Exempt.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: Not exempt.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: I might need a clarification here, since -- so we can have it as a Class II device, but have it exempt from --

MS. SHULMAN: Pre-market notification, so a company would not be required to submit a 510(k).

DR. ZERO: Exempt.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Not exempt.

CHAIRMAN SUZUKI: And, I indicate not exempt.

DR. COCHRAN: Jon, I'm going to change my vote to not exempt.

CHAIRMAN SUZUKI: Okay, then summarizing the vote it's 4:1, is that correct?

MS. SHULMAN: Correct.

CHAIRMAN SUZUKI: Consumer and industry representatives.

Ms. Howe?

MS. HOWE: Exempt.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Exempt.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: Not exempt.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Not exempt.

CHAIRMAN SUZUKI: So, the vote is 4:1 in favor of not exempt.

MS. SHULMAN: Thank you.

Number 12, if you know if any existing standards that would apply to the device sub-assemblies, components, device materials, you can list them at this time. If not, we can just write none. Right, there are two in the presentation besides the two listed in the presentation.

CHAIRMAN SUZUKI: Does the Panel have any questions regarding the existing standards?

None.

MS. SHULMAN: Thank you.

Now you will vote on the two forms as filled out as a Class II device with that identification requiring pre-market notification, and you will vote to approve those forms or not.

CHAIRMAN SUZUKI: Okay. We'll go around and we'll vote on the entire submission presentation.

Dr. Cochran?

DR. COCHRAN: Approve.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Approve.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Approve.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Approve.

CHAIRMAN SUZUKI: The Chair votes approve.

Consumer and industry representatives.

Ms. Howe?

MS. HOWE: Approve.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Approve.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Approve.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Approve.

CHAIRMAN SUZUKI: Okay. Note for the record that this was unanimous.

MS. SHULMAN: Thank you very much, and now we will collect the forms from this classification.

DR. ZERO: Excuse me.

We should go back on the first form and write in the classification recommendation?

MS. SHULMAN: Yes, please, on general

device classification questionnaire, the classification recommendation is Class II.

CHAIRMAN SUZUKI: So, the indication is, under classification recommendation, II, non-exempt.

MS. SHULMAN: Thank you.

CHAIRMAN SUZUKI: Okay, the Chair would like to call for a 15 minute break.

(Whereupon, at 10:30 a.m., a recess until 10:45 a.m.)

CHAIRMAN SUZUKI: Next on our agenda is FDA's presentation of the proposed classification of Retraction Cords, and I would like to ask Dr. Robert Betz, Dental Officer for the FDA presentation on Retraction Cord.

DR. BETZ: I was supposed to speak this afternoon, but I'm going to say good morning. My name is Dr. Robert Betz, I'm here to present the gingival retraction cord for your consideration.

My presentation will include the device description, an intended use, and two indications for use, one medical device report of an adverse event, a table of risks and mitigations for those risks, and

FDA's proposed classification for this product.

Gingival retraction cords are composed of single or multiple strands of cotton or cotton polyester fibers. They are available in various diameters and may be twisted, braided or knitted. Retraction cords are inserted into the gingival sulcus around teeth with subgingival tooth preparation margins. They are left in place for several minutes and are removed immediately before placement of dental impression materials.

The purpose of the cords is to press outward on free marginal gingival tissues, pre-creating space, permitting dental impression materials to flow around tooth margins and accurately capture them in the dental impression.

Most retraction cords available prior to 1976 contained no drug component or were impregnated with epinephrine as the hemostatic agent. Aluminum chloride was initially substituted for epinephrine because of adverse events related to epinephrine's effects on the cardiovascular system.

Other hemostatic drug components presently

on the market include, but are not limited to, ferric sulfate and zinc phenosulfate. I take that back, that was -- yeah, ferric sulfate, okay.

Gingival retraction cords with or without drug components are intended to be used as an aid in the taking of dental impressions, to assure capture of subgingival preparation margins.

Although there is only one intended use, two indications for use have been identified. Number one, plain retraction cords are indicated for use in sites where there's no gingival bleeding. In addition, plain gingival retraction cords are indicated for use for patients who have a medical contraindication to one of the drug components available with the cords. Number two, gingival retraction cords with a drug component are indicated for use in sites where there is gingival bleeding present.

A recent search of the medical device report database revealed only one adverse event, and I was surprised about this because I'm sure there are more than one, but only one was reported to us. This

report was related to a patient reaction to epinephrine in a gingival retraction cord. The patient was discharged from a trauma center after three hours of testing and monitoring, no active treatment was required.

Risks to health include adverse tissue reactions caused by the retraction cord material itself and adverse reactions to the drug component. Retraction cord fibers may be embedded in circular sulcular tissues, causing a foreign body reaction. It is also possible that a patient may be allergic to one of the cord components itself.

There are also drug reactions possible that may include allergic reactions to the drug component and adverse cardiovascular events. There is also a possibility of interactions with other medications that the patient may be taking.

Improper use may result in damage to the dental gingival attachment, resulting in deepening of the gingival crevice or sulcus, and/or recession of the gingival margin. There is also a very remote risk of inhaling a piece of retraction cord into the lung.

Swallowing a piece of cord does not appear to pose a significant safety issue.

Measures that may be used to mitigate these risks include device labeling, biocompatibility testing, appropriate material specifications, and a placement of a prescription only warning on the device label.

Consultative reviews have been requested from the Center for Drug Evaluation and Research in the past. It is proposed that CDER continue to review any drug components present in this device.

Proper device labeling and the limitation of use of this device, to use by appropriate healthcare professionals only, may facilitate the exercise of due diligence and care in the placement of these devices.

FDA is proposing a two-tier classification for this device, one for retraction cords with a drug, and one for those without. There are safety issues related to the presence of the drug component. Review of these drug components by the Center for Drugs is necessary to assure, or at lest we feel that it's

necessary, to assure that the device is safe for use in patient populations.

The proposed identification for the gingival retraction cord device without a drug component is as follows. Identification, a gingival retraction cord without a drug component is a single or multiple stranded cord that is not impregnated with drug components. Gingival retraction cords without a drug component are intended to be used as an aid in taking accurate dental impressions of the margins and tooth preparations by displacing unattached gingival tissues adjacent to the margins of those tooth preparations.

FDA is proposing that retraction cords that have no added drug component be placed in Class I, with general controls. We also propose that the devices be exempted from requirements for the submission of a pre-market notification or 510(k).

The identification for a gingival retraction cord with a drug component is as follows. Identification, a gingival retraction cord with a drug component is a single strand or multiple stranded cord

that is impregnated with drug components. Gingival retraction cords with a drug component are intended to be used as an aid in taking accurate dental impressions of subgingival margins of tooth preparations by displacing unattached gingival tissues and minimizing bleeding that may interfere with the impression process.

When a drug component is present, FDA is proposing that the retraction cord be regulated as a Class II device, and be subject to pre-market notification procedures. We also propose that a guidance document serve as one of the special controls for this device. This guidance document will assist device manufacturers in the submission of data and information required or necessary for pre-market notification or 510(k).

Thank you.

Any questions?

CHAIRMAN SUZUKI: Thank you, Dr. Betz.

I'd like to ask the Panel if they have any questions for Dr. Betz.

Dr. Bakland?

DR. BAKLAND: When the device is not classified, is there a regular procedure for reporting adverse reactions to that?

DR. BETZ: It's my understanding that FDA accepts medical device reports for all devices, whether they are regulated, classified or not.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Under the other drug components, can you give us an idea of the range of what other meant?

DR. BETZ: There may be one or two more. I searched and I could find those two. There are -- there's at least one other that I'm aware of, that with my wonderful memory it's slipped my memory, but there may be more, one, maybe two at the most.

CHAIRMAN SUZUKI: Okay.

Other questions?

Okay, we now have an open comment session concerning the proposed classification of the retraction cord device. In addition to the two already indicated wishing to speak, I'd like to ask if there's anyone else in attendance who wishes to

address the Panel.

First, I'd like to call Mr. Henry Vogelstein for Coltene/Whaledent to address the Panel.

MR. VOGELSTEIN: Good morning. I'm Henry Vogelstein. After having been employed by Coltene/Whaledent for 33 years, I am now a consultant to that company, and I receive a fee for my consultancy, and my expenses for this occasion will be fully paid by Coltene/Whaledent.

Good morning. Thank you very much for allowing me to address this panel. We welcome this. I really don't have very much to say, because the FDA presentation answered my prayer. We agree with what has been said.

I do want to point out, though, that the MDR report, the one MDR report that is on record, I believe that there are many more out there that have not been reported, because generally if an epinephrine occurrence takes place in a dentist's office, to me it seems an indication as though the dentist really didn't do his job in taking down the problematical history of the patient, and that may frequently result

in an epinephrine adverse event.

So, thank you very much. I appreciate this opportunity.

CHAIRMAN SUZUKI: Okay.

Does the Panel have any questions for Mr. Vogelstein?

Thank you, Mr. Vogelstein.

Our next open comment is by Mr. David Watton, Pascal Company.

MR. WATTON: Good morning. I'm the President of Pascal Company, and I think you've all read the letter I wrote earlier.

I guess my issue is with this, is whether all retraction materials will be covered by this or only the cords. There are a number of other products that are used, such as dentists will be familiar with Exposil, which has aluminum sulfate in it, and it is used, basically, in the same fashion as cords. But, I see no real mention of that particular product in this classification. So, that might be something that the board wants to consider.

The other issues are the fact that there

are really three different types of products when you are talking about retraction cord. You have the plain cord, which is purely mechanical displacement, you have the ones that have hemostatic qualities, like -- the other one drug item is aluminum sulfate that is commonly used -- those products, as I say, within Europe are still classified as Class I devices, mainly because their effect is not systemic at all, which is physical displacement.

Then you have the epinephrine cords, which are systemic in the way they work. It would seem to me that rather than treat them all as the same, it would make more sense to make a distinction between the three types, rather than just say, oh, they are the same. Obviously, you are running more of a risk with epinephrine.

But, the other thing I might point out is, most of the plain cords are usually soaked by the dentist in some material elsewhere, which is uncontrolled. The dentist can merely put it in Hemodent or any other such product, which is an aluminum chloride product, and they have no idea how

much they are placing on the cord before they apply it.

So, in a way, retraction cords that have a specific medicament are safer than the uncontrolled use of plain cords, so there are a number of issues I think that need to be addressed with this, beyond just looking at retraction cords in isolation, all the methods of retraction should be probably reviewed for classifications thereof.

Thank you.

CHAIRMAN SUZUKI: Okay, thank you, Mr. Watton.

Does the Panel have any questions for Mr. Watton?

Yes, Dr. O'Brien?

DR. O'BRIEN: Yes. The FDA has proposed two classifications, the one the plain retraction cords, not containing medicaments, but then a second one. But now, you are proposing three.

MR. WATTON: Not really. I just -- as I say, within Europe they classify all the ones with just plain hemostatic materials as Class I as well.

Whether then just having the two tier with plain cords, and then all medicaments.

So, all I'm asking is really that one needs to bear in mind the distinctions thereof.

CHAIRMAN SUZUKI: Do you go along with the proposed -- the FDA proposal for two, Types I and II?

MR. WATTON: Yes, I do.

CHAIRMAN SUZUKI: All right.

Dr. Bakland?

DR. BAKLAND: The first material that you mentioned, I'm not personally familiar with, could you describe that? I thought I heard you say there's a material for retraction without cords?

MR. WATTON: That is correct, Exposil is a product that is, I guess, a clay-based material. There's some other new materials that are out there as well, that are for exactly the same purpose, but they are not strictly speaking retraction cords, especially by the definition thereof. And yet, that has not been addressed in this classification.

DR. BAKLAND: And, the name again of that?

MR. WATTON: Exposil.

DR. BAKLAND: Okay.

CHAIRMAN SUZUKI: Dr. Zuniga?

Dr. Runner would like to clarify.

DR. RUNNER: Just a comment that we are classifying the pre-amendments device, any of these newer types of cords would be found substantially equivalent to the cord. So, you really don't have to look at those new types of devices here, just the pre-amendments device, which was the cord.

CHAIRMAN SUZUKI: Thank you, Dr. Runner.

There's a question from a panelist, Dr. Zuniga?

DR. ZUNIGA: This is more for my information. I don't use this material in my practices, but does the industry regulate, or recommend, I shouldn't say regulate, or provide guidance for the maximum amount of impregnated material per patient?

MR. WATTON: No, that has -- I mean, there are contraindications on the literature, but it's been somewhat self-policing all these years, as far as the recommendation. Some people don't even have

specifications -- written specifications on the label as to the quantity of material that is on the cord.

So, no, there has been no unified system.

CHAIRMAN SUZUKI: Okay. Other questions?

Would you like to comment?

Well, at this point we do have an open comment session regarding this classification, so if there are other members that would like to present in the audience please approach the microphone and identify yourself for the record.

So, I will call on Mr. Vogelstein, who would like to comment again.

MR. VOGELSTEIN: I'd like to help clarify on the newer impression methodologies. Coltene/Whaledent has a device that is essentially an impression material. It is classified and has been accepted as both an impression material and a retraction cord. So, it is an impression material that is extruded into the sulcus, and the nature of the material makes it expand and open up the sulcus, and then very easy to remove it afterwards. That is another one of these newfangled ideas that are out

there.

CHAIRMAN SUZUKI: Okay, thank you, Mr. Vogelstein.

Other questions or comments from the Panel?

Any questions or comments from the audience?

If not, I'd like to ask if Ms. Shulman can lead us into the classification forms.

MS. SHULMAN: Okay.

Thank you again. I gave everyone two forms, because we are going to go through this twice, because this is what we call a split regulation, so we are going to go first through the one, retraction cord without a drug, and then we'll go through, again, with the drug.

So, again thank you very much. If you can please put your name, the date, the generic type of device, and the first one is the retraction cord without a drug. Okay.

CHAIRMAN SUZUKI: Okay, we can proceed then with number one.

MS. SHULMAN: Question number one, is the device life-sustaining or life-supporting?

CHAIRMAN SUZUKI: Okay, I'll go around the table again, beginning with Dr. Cochran.

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Our consumer and industry representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Thank you.

Question number two, is the device for use which is of substantial importance in preventing impairment of human health?

CHAIRMAN SUZUKI: Okay, going around again.

Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Consumer and industry reps.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Thank you.

Number three, does the device present a potential unreasonable risk of illness or injury?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

MS. SHULMAN: Okay.

Number four, did you answer yes to any of the above three questions? The answer is no.

We'll go to number five, is there sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness?

CHAIRMAN SUZUKI: Okay.

Dr. Cochran?

DR. COCHRAN: Yes.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Yes.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Yes.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Yes.

CHAIRMAN SUZUKI: Dr. Demko

DR. DEMKO: Yes.

MS. SHULMAN: Thank you.

Okay, we have classified the device into Class I. So, we may skip questions six, seven, eight, nine and ten.

Question 11, the needed restrictions, the first one, the prescription statement, only upon the written or oral authorization of a practitioner licensed by law to administer the use of the device, and then the other two are added on or any other, use only by persons with specific training or experience in its use, and use only in certain facilities. This is a prescription device.

CHAIRMAN SUZUKI: Okay.

Dr. Cochran?

DR. COCHRAN: The first box.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: First box.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: I would say the first two boxes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: First box.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: First two boxes.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: The first box.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: May I ask a quick question before I answer? The second box, does that imply that a dentist may direct, say, an assistant to perform the procedure?

CHAIRMAN SUZUKI: Dr. Betz should probably answer that question.

DR. BETZ: There is a potential for abuse of this particular device by non-licensed practitioners.

Can you repeat the question one more time?

DR. BAKLAND: The question was whether the second box would imply that a dentist may instruct a

dental assistant to perform the procedure with the cord.

DR. BETZ: No, no, we are not recommending that.

DR. BAKLAND: in that case, the first box.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Thank you, just for clarification, these boxes add on top of each other, so the first one is prescription statement, and then the second one would be in addition to that.

CHAIRMAN SUZUKI: So, just for further clarification, if the first box is checked, the prescription actually has to be written to the patient's chart before using this product?

MS. SHULMAN: We would not get into that as the FDA, that would be in the practice of medicine how you would deal with that.

CHAIRMAN SUZUKI: Dr. Runner?

DR. RUNNER: It's, basically, a prescription device, meaning that the patient is not going to go out and buy their own retraction cord over the counter. They could get it from their dentist,

which is pretty reasonable. Most people aren't going to buy it for themselves.

And, in terms of the two items, the training means sometimes in high-risk devices you need specific training to use a device that you would recommend.

We don't really have any say about what a dentist can do with their own assistants. That's the practice of dentistry or medicine in a particular state.

So, yes, a dentist could say to their assistant, use this, but that's not what we regulate. We regulate what the manufacturer can say about the device.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Just as further clarification so I can uncheck or preserve my check, so if I check the second box that would imply that there would have to be specific described training for the use of this?

DR. RUNNER: That's usually what it implies. I think that's usually for Class III type devices, where we are recommending that a particular

practitioner have specific training in use of devices, like a TMJ implant. But, I don't --

DR. ZERO: So, this would be beyond dental school training then.

DR. RUNNER: I believe so, yes.

DR. ZERO: Okay, so I will uncheck my box.

CHAIRMAN SUZUKI: Uncheck.

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Okay.

And, the last consultant, Dr. Demko?

DR. DEMKO: First box.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Thank you, we'll move on to the supplemental data sheet.

Okay again, the generic type of device, please place your name on the sheet, the Advisory Panel, and then question three, is the device an implant? No.

CHAIRMAN SUZUKI: And, just for clarification, the generic type of device should be Retraction Cord (without drug), is that correct?

MS. SHULMAN: Yes, thank you.

Okay, I was just pulling up the indication for use, question four, the indications for use in the device labeling, and it is the first one on this overhead. You can say on your sheet, as presented in the Panel meeting, or you can make any comments now that you would like to see to the indication for use as presented.

CHAIRMAN SUZUKI: Any comments, questions? I think we'll just take a vote at the end of the form, if that's okay with everybody on the Panel.

MS. SHULMAN: Thank you.

Number five, the identification of any risks to health presented by the device, and we have put this overhead up so you can make any comments or add to it, and if there are no comments we can move on to the next question.

CHAIRMAN SUZUKI: Would this slide also include drug components, and what we are voting on is without drug?

MS. SHULMAN: Correct, thank you, this one does ignore anything that has to do with the drug.

Okay, if there are no comments we'll move

on to question six, the recommended Advisory classification there would be Class I. The priority only applies to Class II or Class III devices, so we don't have to go through that.

Number seven we may skip because it is not an implant or life-supporting or life-sustaining.

Question eight, summary of information including clinical experience or judgment upon which the classification recommendation is based, you may say it was presented in the Panel meeting or you may add anything else at this time you wish to.

Okay, if there's no further comments on that, question nine, the identification of any needed restriction, any additional one besides the prescription use labeling.

If there are no questions there, we'll go to number ten, if the device is recommended for Class I recommend whether FDA should exempt it from registration listing, pre-market notification, records and reports, good manufacturing practice. You can choose any or all of the above or none of the above.

DR. COCHRAN: What was the FDA

recommendation, it was exempt, but --

MS. SHULMAN: From pre-market notification, B.

CHAIRMAN SUZUKI: Any other questions from Panel members?

DR. COCHRAN: Could Dr. Betz maybe comment on A, C or D also?

DR. BETZ: This particular product is in contact with tissues that absorb materials into the bloodstream quite readily, and, therefore, we would, hopefully, want to have a fairly close handle on it. So, I would believe that registration, and listing, and records and reports would be important for this particular product.

Did that answer your question, along with GMPs.

CHAIRMAN SUZUKI: On this side of the table first, Dr. Bakland?

DR. BAKLAND: Yes, if we are talking about the cord without any impregnation, would your comments still apply?

DR. BETZ: Yes, yes, because the cord may

have something in it other than a medication, sizing like that which would come in a brand new shirt from the store, something to keep the fibers from separating. There are any one of a host of things that are possible.

CHAIRMAN SUZUKI: Okay.

Dr. Zero?

DR. ZERO: Yes. Along those lines, the fact that the plain cord is typically used in combination with other medicaments, is that of concern here?

DR. BETZ: Again, we were regulating something that was pre-existing pretty much in `76. Other products, like Hemodent, are separate from this, and as such we wouldn't regular them as such with this particular classification.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: If the product is exempt from pre-market notification, but needs to be registered and records have to be kept, how does the manufacturer do this with the FDA?

DR. BETZ: Well, there are forms for registering a listing.

DR. O'BRIEN: Separate forms then?

DR. BETZ: The company needs to keep a master device file for everything that's there, that will enable them to find out whether it trips the exemption or not, and if they don't have the master file they won't know whether it does or not.

DR. O'BRIEN: When does the registration need to take place, upon marketing?

DR. BETZ: Before marketing.

DR. O'BRIEN: Before marketing.

CHAIRMAN SUZUKI: With regard to good manufacturing practice, is there a quality control issue with respect to other manufacturing of these cords? Has that ever been a question before?

DR. BETZ: Not -- I'm not aware of any particular stuff. Obviously, we want decent quality cords, and that which hasn't been dragged through the ground, the dirt. So, there are certain quality issues that do apply.

CHAIRMAN SUZUKI: So, that's never been

raised as a question before?

DR. BETZ: No.

CHAIRMAN SUZUKI: Okay.

DR. BETZ: Thank God.

CHAIRMAN SUZUKI: Okay.

Dr. Zero?

DR. ZERO: Are there any ISO guidelines for these products?

DR. BETZ: Only the ones we mentioned, the 10993, the biocompatibility, which would take care of the material itself.

DR. ZERO: But, not any of the--

DR. BETZ: Oh, and 7405 is the dental corollary to that, yes. No other statements that I'm aware of, no.

CHAIRMAN SUZUKI: Okay, any other comments, questions?

DR. O'BRIEN: One more question.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: Do you know if the American Dental Association has any standards or certification

procedures relating to these products?

DR. BETZ: I would believe they have some kind of a -- they do not? I've been told, no, they do not.

CHAIRMAN SUZUKI: Okay.

Ms. Shulman?

MS. SHULMAN: So, in addition to B, pre-market notification, was there anything else that you felt that it should be exempt from?

Okay, so that would be B, pre-market notification.

Number 11 we may skip because that only has to do with Class II devices.

Number 12, if you know of any other ones besides the ones mentioned, existing standards, then you can list them at this point.

Okay, if there are none of those, we can vote on both sheets as combined, as a Class I, exempt device, from pre-market notification.

CHAIRMAN SUZUKI: Okay. So, I'd like to ask if you are in favor or opposed to the device, beginning first with Dr. Cochran.

DR. COCHRAN: Approve.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Approve.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Approve.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Approve.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Approve.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Approve.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Approve.

CHAIRMAN SUZUKI: Dr. Demko

DR. DEMKO: Approve.

CHAIRMAN SUZUKI: It's unanimous in favor.

MS. SHULMAN: Thank you.

Now we are going to go on to the sheets again and do the retraction cord with drug.

So again, please fill out your name on the

top, the date, the generic type of device, and we'll begin with question one again, is the device life-sustaining or life-supporting?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

MS. SHULMAN: Okay, thank you.

Question two, is the device for use which

is of substantial importance in preventing impairment of human health?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

MS. SHULMAN: Thank you.

Question three, does the device present a potential unreasonable risk of illness or injury?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Yes.

CHAIRMAN SUZUKI: Okay, it's a yes vote, 3:1.

MS. SHULMAN: Thank you.

Question four, did you answer yes to any of the above three questions? That answer is yes. We

will go to number six.

Is there sufficient information to establish special controls in addition to the general controls to provide reasonable assurance of safety and effectiveness?

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Yes.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: I think I might need a clarification. So, if it's requiring special controls this would be --

MS. SHULMAN: Class II.

DR. ZERO: Class II.

Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Yes.

CHAIRMAN SUZUKI: Mr. Schechter?

Representatives.

MR. SCHECHTER: Yes.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: Yes.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Yes.

CHAIRMAN SUZUKI: Yes vote 3:1.

MS. SHULMAN: Thank you.

Question seven, if there is sufficient information to establish special controls to provide the reasonable assurance of safety and effectiveness, please identify below the special controls needed to provide such assurance.

There was a guidance document presented, and then the additional ones, performance standards, tracking guidelines or anything else.

CHAIRMAN SUZUKI: And, the FDA recommendation?

MS. SHULMAN: Guidance document.

CHAIRMAN SUZUKI: Was guidance document.

Okay.

Dr. Cochran?

DR. COCHRAN: Guidance document.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Guidance document.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Guidance document.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Guidance document.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Guidance document.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Guidance document.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Guidance document.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Guidance document.

CHAIRMAN SUZUKI: Okay, unanimous, guidance document.

MS. SHULMAN: Thank you.

Questions eight, and nine, and ten we may skip because that has to do with performance standards

or Class III devices.

So, again, we go to question 11, the prescription use statement, and it is a prescription device, but is there any other additional restrictions that you feel are needed for this device?

CHAIRMAN SUZUKI: So, you are recommending upon the written or oral authorization?

MS. SHULMAN: Correct.

CHAIRMAN SUZUKI: Of the practitioner.

MS. SHULMAN: Yes.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: First box.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: First box, but I have a question.

Does this include warnings, in terms of other? Would that go under the first box plus warnings?

MS. SHULMAN: No, warnings would go into the labeling section of the guidance document.

DR. O'BRIEN: That's not included here.

MS. SHULMAN: Right.

DR. O'BRIEN: Okay, first box.

CHAIRMAN SUZUKI: Okay.

Dr. Zero?

DR. ZERO: First box.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: First box.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: First box.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: First box.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: First box.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: First box.

CHAIRMAN SUZUKI: Unanimous, first box, written or oral authorization.

MS. SHULMAN: Okay, thank you.

We can move on to the second sheet.

Again question three, is it an implant? No.

Four, the indications for use. The second one shown, the retraction cords with a drug component are indicated for retraction of tissues and plates where tissues are bleeding and there are no medical contraindications.

If you agree with that you can say as presented, or you may add any other comments you want at this time.

Okay, there seem to be no comments.

CHAIRMAN SUZUKI: No comments from the Panel?

Okay, we can continue.

MS. SHULMAN: Number five, the identifications to the risks to health. Again, they are up on the overhead. If there's any additions you can add them at this time, if not you can say as presented during the Panel meeting.

No additional comments, we can go on to question six, the classification is Class II. Again, the priority high, medium or low, how fast would you like us to work on the proposed and final regulation for this.

CHAIRMAN SUZUKI: Okay, I'll poll the Panel members.

Dr. Cochran?

DR. COCHRAN: Low.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Medium.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Medium.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Medium.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: High, and I reference my previous comments.

CHAIRMAN SUZUKI: Okay.

Mr. Schechter?

MR. SCHECHTER: Low.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: Low.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Low.

CHAIRMAN SUZUKI: It's 3:1 in favor of

medium.

MS. SHULMAN: Thank you.

Question seven we may skip because it's not an implant or life-sustaining or life-supporting.

Number eight, the summary of information upon which the classification recommendation is based, you may say as presented in the Panel meeting or you can add anything else you wish to at this time.

No comments, then we'll go to question nine, identification of any needed restriction on the device, special labeling. We already have the prescription use, anything you wanted to add?

DR. O'BRIEN: In terms of labeling, there could be an interaction between the presence of epinephrine and local anesthetic with the use of a cord that had a high level of epinephrine in it. So, the warning might include some warning about an interaction between the anesthetic and the retraction cord.

CHAIRMAN SUZUKI: That was Dr. O'Brien that just spoke.

MS. SHULMAN: Thank you.

DR. ZUNIGA: Jon?

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: One more consideration may be wanting to add a restriction, and that is, some indication of the maximum amount of cord per individual.

MS. SHULMAN: That is fine, thank you.

CHAIRMAN SUZUKI: As measured by length of cord or number of teeth involved, or both?

DR. ZUNIGA: That's not my decision. I said per person, but that could include children, so I don't know.

CHAIRMAN SUZUKI: Okay. We'll make that note.

MS. SHULMAN: Thank you.

We'll move on to the second page, question ten we may skip.

Question 11, is the device is recommended for Class II, recommend whether FDA should exempt it from pre-market notification.

CHAIRMAN SUZUKI: Okay, I'll ask the Panel members on this issue, question number 11.

Dr. Cochran?

DR. COCHRAN: Not exempt.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Not exempt.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Not exempt.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Not exempt.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Not exempt.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Not exempt.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Not exempt.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Not exempt.

CHAIRMAN SUZUKI: Okay, unanimous, not exempt.

MS. SHULMAN: Thank you, not exempt.

Question 12, any other existing standards

that you know of.

CHAIRMAN SUZUKI: Okay, any questions from Panel members?

None.

MS. SHULMAN: Okay, thank you.

At this time, we'll vote on the forms, both forms, as completed as a Class II device, requiring pre-market notification, subject to the guidance document.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Okay, we'll vote on the entire supplemental data sheets.

Dr. Cochran?

DR. COCHRAN: Approve.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Approve.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Approve.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Approve.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Approve.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Approve.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: Approve.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Approve.

CHAIRMAN SUZUKI: Okay, it's unanimous.

MS. SHULMAN: Thank you very much.

CHAIRMAN SUZUKI: At this time I will call for adjournment for lunch. We have an hour and 15 minutes for lunch.

Thank you. We'll come back at 1:00.

(Whereupon, the meeting was recessed at 11:34 a.m., to reconvene at 1:00 p.m., this same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:02 p.m.

CHAIRMAN SUZUKI: And, I'd like to welcome Dr. Salomon Amar, who has joined our Panel for this afternoon.

Okay, next on our agenda is FDA's presentation of the proposed classification of oral wound dressing, and is Ms. Angela Blackwell present?

Okay, Ms. Blackwell?

MS. BLACKWELL: Hello, my name is Angela Blackwell, and I'm speaking today about the classification of oral wound dressings.

The sections of my presentation are description of oral wound dressings, the regulatory history, the adverse event reports from the Medical Device Reporting database, the risks to health that we've identified, and their mitigations, and our proposed classification.

Oral wound dressings are intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief.

For prescription use, they are used after periodontal surgery or radiation therapy. For over-the-counter use, they are for relief from irritation of oral appliances, aphthous ulcers or other oral wounds.

Oral wound dressings may contain a drug or biologic, but the primary mode of action is provided by the physical barrier property of the device component.

Pre-amendment devices that were used in the practice of dentistry before 1976 include the original Orabase, Orabase with Kenalog, and Coe Pak.

Fifteen 510(k)s have been cleared for oral wound dressings. Historically, these devices have been regulated under different classifications or remain unclassified. One was cleared as a dental cement or as periodontal wound dressings, and ten as unclassified hydrogel wound dressings containing drugs or biologics.

The objective today is to classify these into one classification for oral wound dressings.

The database contains ten adverse event

reports. Nine are reports of allergic reactions to a periodontal wound dressing, and there's one report of adhering mucosal tissue to a tooth.

The risks we have identified are adverse tissue reaction to the device or the drug component. That includes the potential of accidental ingestion, and improper use, particularly, the problem of adhesion of tissues.

Proposed mitigations are biocompatibility testing, labeling, a drug review by CDER, preclinical testing, and labeling.

FDA's proposal is the following. Identification, oral wound dressings are devices intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief.

Our recommendation is Class II with special controls. The special control for this device would be the guidance document, Class II Special Controls Guidance document, Oral Wound Dressings.

Thank you.

Are there any questions?

CHAIRMAN SUZUKI: Okay. Does the Panel have any questions for Ms. Blackwell?

Dr. O'Brien?

DR. O'BRIEN: Yes. You mentioned one type was the ten hydrogels, do you know, specifically, what type of hydrogel that was?

MS. BLACKWELL: There's more than one type that's on the market. Most of them contain something like aloe vera or something, that's the drug component that's in them. It's a very minimal amount, in some cases it's a below therapeutic dose, but then there's other ones that contain an active ingredient like benzocaine or Kenalog.

DR. O'BRIEN: What would be the hydrogel matrix then? Would they be altunates, or some others?

MS. BLACKWELL: Well, they could be any of those things. Some of the things we've seen are like carboxymethylcellulose. There's various different ones on the market. Some of them are -- some of them look like kind of a dry product that you place, and then the moisture from your mouth turns it into a gel, and others are a powder in a bottle that you pour the

water in up to the measurement that's shown on the bottle and you shake it up. So, you drink it and swish it around. Those are -- most of the swishing ones I think are for patients who have more than one sore, you know, so where you want to put it in various places at the same time, without having to, you know, try to get in your mouth and touch every sore.

Some patients with braces, for instance, or the prescription products are that way.

DR. O'BRIEN: Thank you.

CHAIRMAN SUZUKI: Okay.

Ms. Howe?

MS. HOWE: You had mentioned that there are over-the-counter and prescription forms. Do they differ in any way, any components that are different?

MS. BLACKWELL: As far as the ingredients, no. There are some that are specifically for patients who have had radiation therapy, or periodontal surgery, you know, for some other types. There's one that -- some types are used after periodontal surgery over the patient's stitches, and those are used by the clinician, and then the ones that are used after some

types of radiation treatment or some other -- even other types of treatment that would cause sores in the patient's mouth, many of those products that are labeled specifically for that, they are used more frequently, and they are kind of -- it's kind of an as needed as opposed to the over-the-counter which say, you know, don't use more than, you know, four times a day or six times a day, and that's because those patients who have those type of diseases or symptoms they are under a doctor's care. And so, that's who it's meant for. You know, it may be similar to an over-the-counter product, sometimes there's even the same ingredients, but the labeling is different.

CHAIRMAN SUZUKI: Okay.

Dr. Amar?

DR. AMAR: Good afternoon.

Could you -- you mentioned some adverse event report on this.

MS. BLACKWELL: Yes.

DR. AMAR: And, some of them were allergic reactions.

MS. BLACKWELL: Yes.

DR. AMAR: Do you know if there were systemic or localized allergic reaction?

MS. BLACKWELL: Some of both.

DR. AMAR: Excuse me?

MS. BLACKWELL: Some of both.

DR. AMAR: And, was there any trend as to how would they develop? Is it quincodema, for example?

MS. BLACKWELL: Yes, they were all from periodontal wound dressings, so it was cases where the patient had had periodontal surgery, and the clinician put the dressing on and the patient had a reaction. In many cases, swelling, redness, your normal allergic reactions, and I believe there were some patients that it progressed to a systemic effect.

Many of the reports were actually filed, I believe, from one practice. You know, basically, we got a report saying we've had -- you know, my practice has had, you know, a bunch of these happen over the years, so, basically, I guess he realized he had kind of a critical mass of them, so he reported them.

I'm sure there's a lot more out there,

because if this one office has all these patients with allergies, I'm sure there's a lot that aren't reported.

CHAIRMAN SUZUKI: Okay.

Dr. Zuniga?

DR. ZUNIGA: My question was, basically, the same, but were there any of the swish Orabase or any of those products that had allergic reaction, or were they pretty much confined to the product of --

MS. BLACKWELL: The only allergic reactions were for periodontal wound dressings.

DR. ZUNIGA: Only, okay.

MS. BLACKWELL: But, there's no way to tell if that's the case on the market. I mean, we get so few reports.

CHAIRMAN SUZUKI: Okay.

Dr. Demko?

DR. DEMKO: Just a simple question. I know that Orabase is over the counter, is Kenalog and Orabase also OTC? I thought that was prescription.

MS. BLACKWELL: I believe that's a prescription.

DR. DEMKO: Okay.

CHAIRMAN SUZUKI: Okay.

Other questions? Comments to Ms. Blackwell?

Yes, Dr. O'Brien?

DR. O'BRIEN: One other question. Does this overlap, like, for example, Orabase with patients who are treating mouth ulcers, such as could rise from Herpes infections or that type of thing?

MS. BLACKWELL: Yes, it could. This is for any type of oral wound. So, basically, the products are the same, they just provide a barrier to cover the sore. Some contain drugs, you know, like the Orabase with Kenalog, and I believe there's some other ones that have been out there for a while that contain drug products.

CHAIRMAN SUZUKI: Yes, there's a series of Xylactin products that also contain different chemical components, too, so are we grouping these together or are we splitting them?

MS. BLACKWELL: They are all grouped together.

CHAIRMAN SUZUKI: With or without drugs?

MS. BLACKWELL: Yes, because we couldn't split them up by -- basically, most of them have drugs, even the ones that don't have something like benzocaine or Kenalog in them, most of the gels have a drug in them that helps form the gel. So, they were grouped, you know -- they were in an unclassified grouping called hydrogels with drug or biologic, because it had a small amount of something in there. It wasn't added, it was just a component of the gel.

CHAIRMAN SUZUKI: So, we're proposing a group classification and whether or not these products contain steroids or not they would still be considered the same.

MS. BLACKWELL: Yes, because the device portion would be, basically, the same. Whether we need a consult from Drugs or not would depend on what else is in there, other than the device. But, the ones that contain drugs, basically, everything else is exactly the same as those without drug.

CHAIRMAN SUZUKI: Okay.

Any other questions?

If not, Ms. Shulman?

We now have an open comment session from the public concerning the proposed classification of wound healing dressings, and I'd like to ask if there's anyone in attendance who would like to present and address the Panel. And, if there is, please approach the microphone and identify yourself.

Yes, sir?

MR. YOST: My name is Kevin Yost. I work for Sunstar Butler, and we have a product that may, perhaps, fit into this category now, and my question goes to I think that last statement, where you were talking about does it have drugs or does it not. It would seem to me that just like the previous discussion, where you were looking at the retraction cords, if there are no drugs involved it seems likes a totally different category than something that does have any kind of metabolic effect on what's going on in the mouth. And, I would question whether a product that is purely mechanical should really be held to the same criteria as one that has a metabolic effect.

And so, I would ask that you consider,

perhaps, there should be two categories.

CHAIRMAN SUZUKI: Okay. Do any Panel members have questions for Mr. Yost?

Thank you.

Okay, anyone else from the audience?

Any questions and discussion on that issue?

DR. BAKLAND: A question.

CHAIRMAN SUZUKI: Yes, Dr. Bakland speaking.

DR. BAKLAND: Yeah, for clarification, you know, between the incorporation of a drug into a device or not, did I understand earlier that if a drug is incorporated into a device there has to be some statement relative to the purpose of that drug, in order to then make it a drug classification rather than just part of the device?

MS. BLACKWELL: For most of these products, the drug has its own indication, because the drug product would have to be marketed for this type of indication, you know, through the Center for Drugs.

So, in the labeling for combination

products, you have an indication for the combined product, and if the drug is cleared for market, you know, in some other form, or in the same form, it has a specific indication.

For instance, if you had a product that had, say, benzocaine in it, benzocaine is an anesthetic, so it has an indication as an anesthetic, but that's not the indication for the wound dressing. The wound dressing is the same indication that you saw, the physical barrier property.

So, there's a difference in the indications, and so on the labeling both are present there.

DR. BAKLAND: So, based on that explanation then, whether or not the device has drugs in it, such as the wound dressing, it still would make sense then to put them all in the same category?

MS. BLACKWELL: Yes, I believe so. The review for the device component is done the same. It's just that if it has a therapeutic level of a drug we have to have additional input from the Center for Drugs, and the device, the combination product

labeling mustn't conflict with the labeling for the marketed drug product.

CHAIRMAN SUZUKI: Other questions, comments?

Okay, Ms. Shulman?

MS. SHULMAN: Just as a matter of clarification first, you all may vote to separate it and make it a split classification if you want. So, if you want to discuss that first before we go through, and then decide to do it all at once, or split the classification, like the last one.

CHAIRMAN SUZUKI: Okay.

Let's open the discussion on that issue then, if anyone would like to comment from the Panel?

DR. DEMKO: Dr. Demko. I would have one question. In all of these adverse reactions to periodontal dressings, were there all medicaments in there or was that just used as a physical barrier?

MS. BLACKWELL: The ones with the allergic reaction don't contain drug.

CHAIRMAN SUZUKI: Okay, any other comments?

Dr. O'Brien?

DR. O'BRIEN: Yes. I have a concern about the ones that do not contain drugs that are sold over the counter, where patients frequently use these for self-medication for ulcers that they have in their mouth, usually will vary in origin, herpes, for example, and they don't do any harm, but they don't really help as a very effective similar medications with antiviral medications. So that, if it is sold over the counter, there should be a warning to the patient that this will not speed up the recovery of that ulcer of a viral nature, and they could get rapid relief by seeing their dentist or physician for appropriate medications that would, not only treat the ulcers, but actually prevent them at early stages.

MS. BLACKWELL: Well, the labeling, basically, is for any type of mouth irritation. So, the patient is probably not going to know what it came from in many cases, but the labeling does say not to use it more than a certain number of days, and if it's more than, you know, I think most of them say seven days, if it persists for more than seven days see your doctor or dentist. So, it's not specifically labeled

for any particular type of ulcer, it's just, basically, if you -- because it's like a Band-Aid, that's the way they are labeled, it's similar to like an oral Band-Aid.

DR. O'BRIEN: Right, but you could help the patient by warning them if they have recurrence of these ulcers that they should see their dentist or physician, because the materials that don't have any medication in them, that there are very much more effective medications with -- materials with medications in them that the dentist and the physician can prescribe, even though they are told to see their -- don't use them over a certain period of time, but by that time the ulcer from the viral herpes infection would be gone probably anyway. So that, it would give patients information that the non-medicated substances have serious limits in terms of what infections patients could have.

MS. BLACKWELL: But, how is the patient going to know whether it applies to him, he doesn't know what caused his ulcer? So, if there's anything there about herpes, they won't know.

DR. O'BRIEN: If they are repeated, not only if they last more than certain time, but if they have a repeated occurrence of these type of lesions.

MS. BLACKWELL: Okay, so you are saying --

DR. O'BRIEN: If they have repeated occurrences they should get a diagnosis.

MS. BLACKWELL: -- okay.

DR. O'BRIEN: Rather than just using the same useless type of material.

MS. BLACKWELL: So, in addition to saying if it persists for more than seven days see your physician, you think the labeling should also say --

DR. O'BRIEN: Repeated occurrence.

MS. BLACKWELL: -- if you have repeated occurrence of these type of mouth sores --

DR. O'BRIEN: Yes.

MS. BLACKWELL: -- to see your doctor or dentist.

DR. O'BRIEN: But, for more effective medication, in other words --

MS. BLACKWELL: Well, see the doctor or dentist, and we don't -- we can't presume what the

doctor or dentist would give the patient.

CHAIRMAN SUZUKI: Stepping aside as chair, I'd like to make a comment also. I see this -- personally, I see this classification of oral wound dressings is really analogous to the retraction cord model that we discussed this morning. I think a product that has drugs in it, like steroids for control of inflammation or immune reactions, or a pain medication to control localized pain, is quite different from a wound dressing that has nothing in it at all, to be merely protective.

Would Dr. Runner like to comment?

DR. RUNNER: I think maybe the word drug is throwing you for a loop here. I think the major drug we've seen is aloe vera. We are not talking about a wide variety of drugs that are not cleared for a specific oral wound indication.

If we were to see an oral wound dressing that would come in with an antibiotic or something else, it would definitely not be something that we are going to be looking at, it would be something that would be sent over the Drugs. It would be a new

indication, et cetera.

We are talking about a set of hydrogels that are mostly over the counter, with aloe vera in non-therapeutic doses as the drug. But, it is a drug. So, we are not talking about -- even I think the Orabase with Kenalog may have been pre-enactment and we never saw it, I think Drugs actually saw those products.

So, I think you can be assured that if there was a new entity placed in an oral wound dressing that it would definitely go to Drugs.

CHAIRMAN SUZUKI: So, you are saying we don't have to deliberate on that today, because that's separate? It will be flagged separately?

DR. RUNNER: Right, right.

I mean, if we were to see an oral wound dressing that would come in with a new drug, let's say, we would send the manufacturer a letter that says, outstanding drug issue, and we'd send it over to Drugs, because we wouldn't have any experience with that.

And, if it had a drug that was a known

entity, we would also send it over to Drugs if it was in a therapeutic dose, we would also send it over to Drugs as a new delivery system for the drug. We are not in the -- the Devices Section is not in the business of reviewing drugs.

They are combination products because these kinds of dressings primarily act by their barrier function, and that's their primary mode of action, not the drug component, if there is a drug component.

CHAIRMAN SUZUKI: Okay.

Dr. Amar, did you have a question?

DR. AMAR: Yes.

CHAIRMAN SUZUKI: Okay.

DR. AMAR: So, basically, if I understand correctly, there's no possibility of drug abuse or excessive use by the public of this kind of dressing that would be over the counter.

DR. RUNNER: Right. I mean --

DR. AMAR: Us as the gatekeeper --

DR. RUNNER: -- right, aloe --

DR. AMAR: -- we'd like --

DR. RUNNER: -- aloe and benzocaine are the two major drugs that we've seen, and those are already over the counter. We also get drug consult.

We are not talking about a wide variety of drugs in these dressings, and the drugs that are there have been in less than therapeutic levels.

CHAIRMAN SUZUKI: Okay, any other comments?

DR. RUNNER: Does that answer the question?

CHAIRMAN SUZUKI: Okay.

I believe we still need a motion to vote on whether or not to split this or whether or not we should keep it the way it is as presented.

Dr. Cochran?

DR. COCHRAN: I'll make the motion that we keep it together.

CHAIRMAN SUZUKI: Okay, is there a second?

DR. AMAR: I second the motion.

CHAIRMAN SUZUKI: Okay, discussion now?

Dr. Lin?

DR. LIN: I just want to comment. I think that you just mentioned this morning that we discussed this retraction cord, the reason we split it up are

two different indications, that is the reason we split it. But, when we talk about wound dressing, that indication isn't exactly the same, it's not the same indication.

CHAIRMAN SUZUKI: Further discussion?

I will call the question then, all in favor of -- would you like to repeat the motion, Dr. Cochran?

DR. COCHRAN: The motion is to keep all these products as one category.

CHAIRMAN SUZUKI: All in favor of keeping the products in one category, just raise your right hand or say aye.

(Ayes.)

CHAIRMAN SUZUKI: Opposed?

Okay, it's unanimous we keep it as one classification.

Okay, if Ms. Shulman can proceed with the classification forms.

MS. SHULMAN: Thank you.

Okay, again, if you can place your name on the top of the sheet, and the date, and the generic

type of device.

Okay, question one, is the device life-sustaining or life-supporting?

CHAIRMAN SUZUKI: I will go in alphabetical order. Dr. Cochran is off the hook since Dr. Amar is now with us.

DR. AMAR: Sorry for being late.

CHAIRMAN SUZUKI: I will begin with Dr. Salomon Amar to question number one?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Unanimous no.

MS. SHULMAN: Thank you.

Question two, is the device for a use which is of substantial importance in preventing impairment of human health?

CHAIRMAN SUZUKI: Okay.

Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Unanimous no.

MS. SHULMAN: Thank you.

Question three, does the device present a potential unreasonable risk of illness or injury?

CHAIRMAN SUZUKI: Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Okay, unanimous no.

MS. SHULMAN: Thank you.

Question four, did you answer yes to any of the above questions, the answer is no.

Then we go to item five, is there sufficient information to determine that general controls of Class I are sufficient to provide reasonable assurance of safety and effectiveness?

CHAIRMAN SUZUKI: Okay, beginning with Dr. Amar.

DR. AMAR: I would say yes.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: 3:2 yes, so Class I.

MS. SHULMAN: Okay, the answer to that is yes, classify in Class I.

DR. ZERO: Mr. Chairman, could we have a review of the voting again, please?

CHAIRMAN SUZUKI: Okay.

Let's call for a revote. I'll begin again with Dr. Amar.

DR. AMAR: Yes.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: The vote is 3:2 no.

MS. SHULMAN: So that you know, I just want to clarify for everyone just on the same page here. If you are voting yes to this question then you are voting for it to be a Class I device. If you are voting no, you are voting for it to either be a Class II or a Class III device.

CHAIRMAN SUZUKI: Do the Panel members understand that?

DR. COCHRAN: And, the recommendation was

by the FDA was Class II.

MS. SHULMAN: Correct.

CHAIRMAN SUZUKI: So, everybody understands that. Okay. That changes it to a no then.

MS. SHULMAN: Okay.

Question five is no.

Question six, is there sufficient information to establish special controls in addition to general controls to provide reasonable assurance of safety and effectiveness?

CHAIRMAN SUZUKI: And, the recommendation was for the guidance document, is that correct?

MS. SHULMAN: Well, first, we have to vote to see if there's sufficient information to establish that special controls.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Because if the answer to that would be no, then we are going to PMA Class III.

CHAIRMAN SUZUKI: Okay, is there sufficient information to establish special controls?

Dr. Amar?

DR. AMAR: Yes.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Yes.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Yes.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Yes.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Yes.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Yes.

CHAIRMAN SUZUKI: It's unanimous 5:0.

MS. SHULMAN: Okay, thank you.

Seven, is there sufficient information to establish special controls, if there is sufficient

information to establish special controls, identify below the special controls needed to provide such assurance. Again, the recommendation from the division was the guidance document, but you are certainly able to check any of the others or list any that you may want added.

CHAIRMAN SUZUKI: Okay, before voting, would the Panel like any further discussion?

DR. O'BRIEN: One question now.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: This is now because of the previous votes, this is going to be a Class II then?

MS. SHULMAN: Correct.

DR. O'BRIEN: Okay.

CHAIRMAN SUZUKI: Okay, any further discussion? Questions?

Okay, Dr. Amar?

DR. AMAR: Guidance document and device tracking.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Guidance document.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Guidance document.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Guidance document.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Guidance document.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Guidance document.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Guidance document.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Guidance document.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Guidance document.

CHAIRMAN SUZUKI: Okay, 4:1 guidance document.

MS. SHULMAN: Thank you.

Okay, question eight and nine we may skip, because it all has to do with performance standards, and ten we may skip because it's only for Class III devices.

Question 11, identify the needed restrictions. Now, correct me if I'm wrong, this was both an OTC and prescription device? So again, there would be both the first one, only upon the written or oral authorization of a practitioner licensed by law to administer the use, and in other we'll also put OTC.

You may add any of the other needed restrictions if you think they are needed.

CHAIRMAN SUZUKI: Okay, questions or discussion on this before we vote?

Dr. O'Brien?

DR. O'BRIEN: Yes. For the over-the-counter labels or directions, that the patient be warned that they should see a physician or a dentist if they have repeated infections or repeated ulcers for proper diagnosis, not only if it lasts for seven or eight days, to warn them that they may have one of these materials that doesn't contain helpful medication, they should get a diagnosis if they have repeated occurrences.

MS. SHULMAN: Thank you, that will be

noted.

CHAIRMAN SUZUKI: Okay.

Any other comments or questions?

If not, I'd like to call upon Dr. Amar first.

DR. AMAR: Only upon written and oral authorization over the counter.

CHAIRMAN SUZUKI: First box, okay.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: First and last box.

CHAIRMAN SUZUKI: Okay, and what is in the last box?

DR. COCHRAN: OTC.

CHAIRMAN SUZUKI: Okay. Dr. Amar also indicates first and last box, correction.

Dr. O'Brien?

DR. O'BRIEN: First and last box, OTC.

CHAIRMAN SUZUKI: Okay. Dr. Zero?

DR. ZERO: First and last box, OTC.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: First and last box, OTC.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: First and last box, OTC.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: First and last box, OTC use.

CHAIRMAN SUZUKI: Okay, consultants.

Dr. Bakland?

DR. BAKLAND: First and last box, and OTC.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: First and last box, OTC.

CHAIRMAN SUZUKI: Okay, it's unanimous first box and the last box, other, designating OTC.

MS. SHULMAN: Thank you.

Okay, now we may move on to the supplemental data sheet.

Supplemental data sheet, again, your names on the top, please, the generic type of device, the Advisory Panel, and is device an implant, no.

So, we'll go to number four, indications for use. Again, that's on the screen, the indications for use, and you can make any corrections or comments, or vote for as it was presented in the Panel meeting.

CHAIRMAN SUZUKI: Excuse me, what was Dr. O'Brien's suggestion on this point?

DR. O'BRIEN: That there be a warning in the OTC materials that patients should seek diagnosis by a physician or dentist if they have repeated lesions.

MS. SHULMAN: And, I believe for that, this will be the general indication for use, and Dr. O'Brien's comments will go under number nine, for any needed restrictions.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: So, if there are no comments on the indications for use, you can write as presented in the Panel meeting.

Number five, the identification of risks to health presented by the device. Again, we have the overhead that was presented during the Panel meeting, or you can make any changes, or comments, or suggestions.

CHAIRMAN SUZUKI: Okay, Dr. Amar has a question.

DR. AMAR: Can I propose to add the

allergic reaction, the potential of having an allergic reaction?

MS. SHULMAN: Certainly, for the identified risk of allergic reactions, did you have -- okay, Angela is saying that's part of adverse tissue reaction, so the labeling would be the mitigation to address that risk.

DR. AMAR: I think in terms of risk to health allergic reactions fall within that, that category.

MS. SHULMAN: Okay, thank you.

CHAIRMAN SUZUKI: In other words --

DR. AMAR: Particularly, in light of the fact that I heard that there were some systemic reactions, the local allergic reaction could become a systemic reaction, then it becomes a health recommendation.

CHAIRMAN SUZUKI: So, Dr. Amar is suggesting a further qualification of adverse tissue reaction to include --

DR. AMAR: Potential --

CHAIRMAN SUZUKI: -- allergy, immunologic.

DR. AMAR: -- yeah.

DR. COCHRAN: My only problem with that is that it's a little bit unconfirmed at this point. I mean, I think I would want, before you put that on the label, I think I'd want a little more documentation, and it bothers me a little bit that most of those came out of one practice. Without sufficient documentation that it was truly an allergic reaction, I'm not sure I would want to go to the point where we'd have to put that on every product that's out there.

DR. AMAR: I think they just --

CHAIRMAN SUZUKI: Dr. Amar is speaking now.

DR. AMAR: -- if I can just answer that, that doesn't hurt to put the allergic reaction, to be honest with you. It prevents any potential ramification. I'm not sure that there are some serious ramifications as to having that into the labeling, and yet it prevents if any allergic -- I could envision even potential allergic reaction to the inert material.

MS. BLACKWELL: Well, may I make a comment, please? We can put information about allergies on

there, but there's no ingredient labeling on these products. So, even if the patient is allergic to it, the dentist has no idea what it is they are allergic to.

CHAIRMAN SUZUKI: Dr. Runner?

MS. BLACKWELL: A general caution, you know, that's why labeling is here as a mitigation, because the patient could have an adverse reaction which could be an allergic reaction or something else. You know, if you consider the allergic reaction to be a systemic reaction.

CHAIRMAN SUZUKI: Dr. Runner.

DR. RUNNER: Just one other comment, this isn't specifically -- these are just identified risks that FDA would be looking for mitigations for, this isn't necessarily in the labeling. So, you certainly could put the potential for allergic reaction here, and we would be looking for biocompatibility data labeling if there was some known allergenic was put in the product, so that we would look for ways to mitigate that risk, it wouldn't necessarily have to be in the actual labeling of the product.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Okay, with those additions was there anything else that should be added to number five, the identification of risks?

Okay, thank you.

Number six, the classification is --

CHAIRMAN SUZUKI: Dr. Demko -- excuse me --

MS. SHULMAN: I'm sorry.

CHAIRMAN SUZUKI: -- Dr. Demko has a comment.

DR. DEMKO: I just want to ask one question. Why is it that the ingredients are not listed? I mean, is that true across the board on these?

(No audible response.)

DR. DEMKO: Okay.

DR. RUNNER: Because devices do not have ingredient labeling in our regulations.

DR. DEMKO: Okay.

DR. RUNNER: We cannot require that.

CHAIRMAN SUZUKI: Okay, Ms. Shulman?

MS. SHULMAN: Question six, classification

is Class II. Again, the priority high, medium or low, how fast would you like us to write the proposed regulation and get the comments and go out with the final reg?

CHAIRMAN SUZUKI: Okay.

To answer this question I'll begin with Dr. Amar, low, medium or high priority?

DR. AMAR: Medium.

CHAIRMAN SUZUKI: Medium.

Dr. Cochran?

DR. COCHRAN: Low.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Medium.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Low.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Low.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Medium.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: As with all my choices

today in this category, I'm assuming that since these products have been unclassified for 30 years that products haven't been held up because they are unclassified. So, given that they are not being held up, I'm voting low again.

CHAIRMAN SUZUKI: Okay, consultants.

Dr. Bakland?

DR. BAKLAND: Low.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Low.

CHAIRMAN SUZUKI: Okay, it's 3:2 in favor of low.

MS. SHULMAN: Thank you.

Question seven we may skip because the device is not an implant or life-sustaining or life-supporting.

Number eight, the summary of information including clinical experience and judgment upon which the classification recommendation was based, we may say as presented in the Panel meeting or you may add anything else you wish to at this time.

If there are no comments, we'll go on to

number nine, the identification of any needed restrictions on the use of the device, for example, special labeling, banning or prescription use, we already know it's prescription and over the counter, and we do have the other labeling restrictions or labeling concerns that were addressed before in the Panel transcript, so is there anything else that should be added at this time?

CHAIRMAN SUZUKI: Any other comments from the Panel?

MS. SHULMAN: Thank you.

Question ten we may skip because that's Class I devices.

Question 11, if the device is recommended for Class II, recommend whether FDA should exempt it from pre-market notification.

CHAIRMAN SUZUKI: Okay, any questions or discussion on this before we take a vote?

Okay, Dr. Amar?

DR. AMAR: Exempt.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Not exempt.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Not exempt.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Not exempt.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Not exempt.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Not exempt.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Not exempt.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Not exempt.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Not exempt.

CHAIRMAN SUZUKI: Okay, 4:1 in favor of non-exempt.

MS. SHULMAN: Thank you.

Question 12, any other existing standards that would be applicable to the device or the device sub-assembly components, the device materials, besides

the ones that were listed in the presentation.

CHAIRMAN SUZUKI: Any questions, comments?

DR. COCHRAN: A comment is that certainly in periodontics today we don't use as many dressings as we used to, so it's kind of interesting that we are classifying this now on a product that we hardly use anymore.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Okay.

CHAIRMAN SUZUKI: Now, at this point do we vote on the entire document?

MS. SHULMAN: Correct, vote on the entire document as filled out as a Class II device requiring pre-market notification, subject to the special control guidance document.

CHAIRMAN SUZUKI: Okay. I'll call first on Dr. Amar on the supplemental data sheet.

DR. AMAR: What do we --

CHAIRMAN SUZUKI: In favor or opposed.

DR. AMAR: In favor.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: In favor.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: In favor.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Approve.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: In favor..

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: In favor.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Approve.

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: Approve.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Approve.

CHAIRMAN SUZUKI: Unanimous.

MS. SHULMAN: Thank you very much.

CHAIRMAN SUZUKI: Next on our agenda is FDA's presentation of the proposed classification of dental electrical anesthesia, and I'd like to call on Mr. Andrew Steen, Mechanical Engineer for FDA, to present.

MR. STEEN: Thank you, good afternoon.

Once again, my name is Andrew Steen, and today I'll be presenting on the proposed classification for dental electrical anesthesia devices. I will cover a brief description and history of this device. I will cover the medical device reports and risks to health presented by this device. I will discuss any applicable standards. And finally, I will give the proposed classification.

A dental electrical anesthesia device provides an electrical current to the tissue surrounding the oral environment by direct electrode connection for the purpose of creating an analgesic and/or anesthetic effect during dental procedures.

This device is connected to the patient in the dental office, just prior to the beginning of the procedure, and removed just after the procedure has been completed. It is intended for use in place of or in conjunction with injectable anesthesia.

These devices were not classified at the time of the Medical Device Amendments of 1976, and there's only one pre-amendment device that has both

the same indications for use, that is, anesthesia or analgesia, and the mode of operation, which is electrical nerve stimulation.

The dental electrical anesthesia devices are currently regulated via the pre-market notification 510(k) process. To date, we have cleared 15 of these devices, and today the agency is seeking the Panel's input on classification.

In order to assess the potential risks associated with the use of this device, the FDA reviewed the adverse events reports contained in the on-line medical device report database. There were a total of nine, four involved nerve damage, three involved burns to the cutaneous area under the electrode pad, one involved an adverse tissue reaction below the electrode pad, and one involved a seizure.

The risk to health for dental electrical anesthesia devices were assessed by the review of the adverse events, published literature, and the 510(k)'s cleared devices. This table identifies those risks. Thermal and nerve damage, which is burns, trauma to the skin or surrounding nerves, could be mitigated by

electrical safety testing. For example, the voluntary standard IEC 60601, and proper labeling. Device failure, that is, circuit failure or power outage, electrical shock, or a patient who is unresponsive to the treatment, could also be mitigated by electrical safety testing, from again IEC 60601 and proper labeling. Cross contamination, that is the improper sterilization of reusable electrode pads, could be mitigated by reprocessing instructions, such as ISO 11134. Adverse tissue reactions, allergic reactions to the electrode pad, could be mitigated by biocompatibility testing from the voluntary standard ISO 10993 or ISO 7405. Electromagnetic interference, such as device interaction with a pacemaker, could be covered by electromagnetic compatibility, which is, once again, in IEC 60601, and proper labeling.

This device is intended to be used by a dental professional, and, therefore, improper use would be mitigated by detailed instructions for use and prescription use only.

Along with the other general ISO standards for sterility, biocompatibility, and electromagnetic

compatibility, I'd like to point out that there is a standard that deals directly with these devices, the voluntary standard IEC 60601-2-10 contains requirements for safety of nerve and muscle stimulators.

And so finally, the FDA proposes to identify a dental electrical anesthesia device as intended to provide an electrical current to the oral environment by direct electrode connection to the tissue for the purpose of creating an analgesic or anesthetic effect during dental procedures. This would be classified as a Class II, special controls, and those special controls employed would be a detailed guidance document addressing the risks to health and mitigations for those risks.

Thank you for your time.

CHAIRMAN SUZUKI: Okay, does the Panel have any questions on this presentation?

Ms. Howe?

MS. HOWE: Is there any special training that dentists are required to have to use these, or is it just assumed that their sales rep instructs them?

MR. STEEN: None that I am aware of within our standards or our guidance, so it would be just what the sales rep trains the doctor. I am unfamiliar with dental schools, so if someone has an idea or learned about this, please let me know.

CHAIRMAN SUZUKI: Other questions, comments?

Dr. O'Brien?

DR. O'BRIEN: Yes.

What's the range of voltages that these deliver to the patient?

MR. STEEN: I don't know.

DR. O'BRIEN: I mean, are they low voltage or high voltage?

MR. STEEN: They are low voltage. They have been -- we get a consult from another branch that does a lot of TENS work, and they are low voltage.

DR. O'BRIEN: What is the evidence that they deliver sufficient anesthesia as compared to other types of anesthesia, removing the suggestion is there evidence of how well they work?

CHAIRMAN SUZUKI: Okay, Dr. Runner?

DR. RUNNER: Maybe there could be some comments from the other dental school faculty. I was never even taught dental electrical anesthesia in dental school. I think it probably is not a widely used phenomenon in dentistry. However, there are some dentists who would utilize these devices.

CHAIRMAN SUZUKI: I'll comment on the three or four dental schools that I've been involved in, but I'd like to solicit my other Panel members first. Other dental school faculty here.

Dr. Bakland?

DR. BAKLAND: If I may ask a question first. In regards to the medical devices, the regulations for TENS, for those, are they similar to what is being proposed for the dental devices?

MR. STEEN: Correct.

DR. BAKLAND: So, it would be comparable.

I will admit that 40 years ago when I took my residency electro anesthesia was my research project, and it was interesting to work with that, and it does, in fact, properly delivered will in fact inhibit the flow of impulses in the nerve.

CHAIRMAN SUZUKI: Okay.

Dr. Amar?

DR. AMAR: In the adverse reactions again, nerve tissue damage, would you comment as to whether, was it reversible or not reversible, or we don't even know?

DR. AMAR: We don't know. The medical device reports were not very clear. One report was a blurred vision in the right eye after use of the device, but it was noted that the patient had a pre-existing condition which may have caused that. Another report was a throbbing of the tooth after the event, but it doesn't say what the dental procedure was, so it may have just been caused from the dental procedure. They are not very clear, they are not very complete. A lot of them are three or four sentence reports that just say something happened.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: What about published clinical studies of the effects of these devices?

MR. STEEN: Of the 510(k)s that I've gone

through, they all contain one report or another that said they worked. I'm not an expert in that area, so I can't comment on that.

DR. O'BRIEN: But, shouldn't there be strong clinical evidence that they work?

CHAIRMAN SUZUKI: Dr. Runner?

DR. RUNNER: I'm sorry, these are devices that are pre-amendment, therefore, they were on the market prior to the 1976 device amendments, therefore, they were grandfathered in. So, therefore, if another manufacturer comes to market with a similar device, in so many words, unless there was some major safety issues relative to these devices we would find them equivalent to pre-amendments devices, and those reports don't seem to compare to the potential number of uses to tip the scales in terms of safety as far as we know at this time.

CHAIRMAN SUZUKI: And, to answer one of Mr. Steen's original questions, I'm on the faculty of four dental schools, and I'm not aware that this procedure is taught in our anesthesia departments.

MR. STEEN: Thank you.

CHAIRMAN SUZUKI: Any other comments?

DR. ZERO: I'd like to add one.

CHAIRMAN SUZUKI: I'm sorry, I didn't see you.

Dr. Zero?

DR. ZERO: The Panel does not have to concern itself with the fact that there is -- we are not being presented with any clinical, well-controlled evidence that they are effective?

CHAIRMAN SUZUKI: Efficacy.

DR. ZERO: Efficacy, I'm dealing with the efficacy side, instead of the safety side.

CHAIRMAN SUZUKI: Okay, Dr. Runner?

DR. RUNNER: You could certainly make the recommendation that we ask for some efficacy data. I don't know that the law would allow us to not approve a device for marketing, save any major safety issues, because it was on the market prior to `76 and was grandfathered in. That's the way our law works at this point in time.

CHAIRMAN SUZUKI: Pre May 28, 1976.

DR. RUNNER: So, it was a grandfathered

device, unless we have some significant information that the safety of the device is in question. It would be pretty hard for us to go back and take them off the market.

DR. ZERO: But, how can we make a good judgment of the safety side of it without understanding. Everything is as risk/benefit analysis in my mind, with any device, so if we don't have any information on the efficacy side, even a minor risk to me would be too much.

DR. RUNNER: Well, you certainly -- I think in your position on a classification panel you can certainly make your concerns known in the questionnaire, and if you have strong desires to have some additional information available in the 510(k)s we certainly could attempt to develop a guidance document that would look at some of these issues.

I just can't say that if we were challenged, in terms of asking for that information, whether that would stand up because of it's pre-amendment status. That's why, I'm not trying to excuse the lack of data, it's just unfortunate the way

the law works.

CHAIRMAN SUZUKI: Okay.

Any other comments, questions, for Mr. Steen?

Okay, thank you.

MR. STEEN: Thank you.

CHAIRMAN SUZUKI: We now have an open comment session regarding the proposed classification of dental electrical anesthesia. I would like to ask if there's anyone in the audience who wishes to address the Panel, please approach and identify yourself for the record.

Okay, seeing none, I'd like to ask Ms. Shulman to lead us.

Oh, one question.

DR. COCHRAN: I'd like to make a comment, that although I understand that this might not have a lot of evidence to support it, it is something that has been studied and has been available for some time.

And, I kind of put it in the group of the periodontal wound dressing as well, whether that's very efficacious or not for the patient we may dispute

that. But, speaking from the consumer advocate side, I'd hate for us to limit something that some dentists might feel is an important tool in their armamentarium.

CHAIRMAN SUZUKI: Okay, thank you, Dr. Cochran.

DR. BAKLAND: May I add to that comment?

CHAIRMAN SUZUKI: Dr. Bakland?

DR. BAKLAND: Probably the biggest disadvantage with electro anesthesia is that it's unpredictable, and it tends to come in cycles. And, if you look at it historically, it goes back to even before chemical anesthesia came in, and was even tried for general anesthesia at one point. And, of course, that had much higher risks, but at least in my observation of local electro anesthesia it's mostly ineffective in most cases. There is some help with it in some instances, but as a general rule it isn't something that I think most dentists will run out and buy, because the success rate just isn't there.

CHAIRMAN SUZUKI: Okay, thank you, Dr. Bakland.

Any other comments?

Okay, Ms. Shulman?

MS. SHULMAN: Okay, thank you.

Again, one more time, please place your name, Panel, the generic type of device, and the date on the top of the sheet.

Okay, question number one, is the device life-sustaining or life-supporting?

CHAIRMAN SUZUKI: Okay, I'll poll the panel, beginning first with Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Unanimous no.

MS. SHULMAN: Thank you.

Number two, is the device for use which is of substantial importance in preventing impairment of human health?

CHAIRMAN SUZUKI: Okay, beginning with Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

CHAIRMAN SUZUKI: Unanimous no.

MS. SHULMAN: Thank you.

Number three, does the device present a potential unreasonable risk of illness or injury?

CHAIRMAN SUZUKI: Okay, Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Yes. My concern is based on the nerve damage, and not knowing if, in fact, that was irreversible damage. I'm not sure if anybody wants to comment on that or bring that up, but that's a concern.

CHAIRMAN SUZUKI: Okay.

Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Unanimous no of the voting members. One concern of the consumer representatives.

MS. SHULMAN: Thank you, and I think we can come back and address that concern, too. Thank you.

Number four, did we answer yes to any of the above questions, the answer is no.

Number five, is there sufficient information to determine that general controls, those are Class I controls, are sufficient to provide reasonable assurance of safety and effectiveness?

CHAIRMAN SUZUKI: Okay, beginning with Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: No.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: No.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: No.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: No.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: No.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: No.

CHAIRMAN SUZUKI: Okay, unanimous no.

MS. SHULMAN: Thank you.

Question number six, is there sufficient information to establish special controls in addition to the general controls to provide reasonable assurance of safety and effectiveness?

CHAIRMAN SUZUKI: Okay, Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Yes.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Yes.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Yes.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Yes.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Yes.

CHAIRMAN SUZUKI: 4:1 in favor of yes.

MS. SHULMAN: Thank you.

Number seven, if there is sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness, identify the special controls needed to provide such reasonable assurance for a Class II device.

Again, the division presented the guidance document, but you are also welcome to check any of the other boxes on the sheet or add any others.

CHAIRMAN SUZUKI: Okay, beginning with Dr. Amar?

DR. AMAR: Guidance document and

performance standards.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Guidance.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Guidance document, performance standards, device tracking, and testing guidelines.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Guidance document.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Guidance document and testing guidelines.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Guidance document, performance standards.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Guidance document, and my experience with IEC standards, especially the specific 60601, that deal with specific device groups, the standards are generally very specific and often difficult to comply with. So, my recommendation would

be that the FDA consider compliance with that standard to be almost a benchmark. Those standards generally handle all kinds of issues dealing with the safety of the device, the performance of the device, patient interlocks, things like that.

So, other than a guidance document or, perhaps, included in the guidance document, to suggest that compliance with that standard be paramount.

DR. ZERO: Point of clarification.

CHAIRMAN SUZUKI: Yes, Dr. Zero?

DR. ZERO: If we go with the guidance document, can we capture that last point with just the guidance document, or do we need to go to one of the other boxes?

MS. SHULMAN: You can capture it in the guidance document, and we would put that the device should be subject to that. A guidance document is not long, so they can address other ways of addressing those concerns.

The performance standard would be law or regulation, in that case they would absolutely have to address it.

CHAIRMAN SUZUKI: Okay.

DR. ZERO: Can I add to my check off of performance standard.

CHAIRMAN SUZUKI: Yes, Dr. Zero.

CHAIRMAN SUZUKI: The consultants.

Dr. Bakland?

DR. BAKLAND: Guidance document and performance standard.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Guidance document and performance standard.

CHAIRMAN SUZUKI: Okay. We do have a consensus on the guidance document. However, there are other discussions that might be applicable for some of the performance standards and testing guidelines. Would you either like to revote on that, or would you like to reopen the discussion, or would you feel comfortable in, because it's a minority opinion now, I'd like to ask the Panel what they'd choose.

MS. SHULMAN: Just one matter of clarification. The guidance document you can put the

requirement into the guidance document. When I said the company doesn't have to follow it, if they don't follow that exactly they would have to explain how they followed something close to it or deviated from it. So, it's not that they would get out of that totally in the guidance document. It's just the performance standard is regulation, written into the regulation, and the guidance document is not.

CHAIRMAN SUZUKI: Okay.

So, despite the fact that some of the Panel members recommended performance standards and testing guidelines, does the Panel feel comfortable in going with just guidance document? Are there any objections?

Okay, Ms. Howe?

MS. HOWE: My concern would be that unless it's specified the performance standards, that if, in fact, the instruction on this equipment is by sales representatives that they be held to some kind of a standard, that they would give the best instruction possible to the user, that they realize that this is an emphatic, as opposed to a suggestion.

CHAIRMAN SUZUKI: Okay.

Dr. O'Brien?

DR. O'BRIEN: Since the device has been around for a long time, and Dr. Bakland indicates that it's a hit or miss type of device, I think we have to consider this as a possible, in the category of medical devices of the 19th Century, that they may work for some patients but not others, and to -- so, I would say, because of the possibility, and I've seen this happen, that devices in dentistry can get new marketing life with a campaign, and young practitioners go to seminars in Costa Rica, whatever, and can get very enthusiastic about things, don't think that this now that seems to be going obsolete couldn't come back again, relatively quickly, depending on the marketing budget.

So that, it needs a lot of controls without clinical studies to back it up.

CHAIRMAN SUZUKI: Okay, so you are recommending further testing guidelines?

DR. O'BRIEN: I would put -- yes, because I would put all the restrictions possible on it, because

it's a suspect device, in terms of clinical effectiveness and possible harm if the voltages were changed in order to make it more effective. And, on the other hand, you could get more side effects from that.

CHAIRMAN SUZUKI: Any other comments or discussion?

Dr. Cochran?

DR. COCHRAN: Yes. If the voltage is changed, then it's not going to fit into the guidance document. So, it seems like to me we are thinking about if you change the device, and we are not looking to change the device, so we are looking at classifying the devices that are on the market, given the low voltage that already exists.

And, I think really market pressure will, indeed, drive it, even if they come out with a big marketing campaign, if it's not effective, then it's not going to be effective. But, it's going to have to fit, based on the guidance document, it's going to have to fit with the pre-existing devices.

CHAIRMAN SUZUKI: In light of the

additional discussion, I'd like to call for an additional vote for sufficient information to establish special controls with respect to performance standards and testing guidelines. Guidance documents is unanimous at this point.

So, beginning first with performance standards, I'll begin first with Dr. Amar, a yes or a no?

DR. AMAR: Yes.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Yes.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Okay, 4:1 in favor of including performance standards.

MS. SHULMAN: Thank you.

CHAIRMAN SUZUKI: Next, testing guidelines, beginning with Dr. Amar?

DR. AMAR: No.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: No.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: 3:2 in favor of no. So, testing guidelines is not included.

MS. SHULMAN: Okay.

CHAIRMAN SUZUKI: So, we will summarize by saying the guidance document and performance standards.

MS. SHULMAN: Thank you.

CHAIRMAN SUZUKI: Okay, a question, Dr. Lin?

DR. LIN: When you mention about performance standard, do you have any idea of what kind of performance standard are we talking about, because when you indicate performance standard in

agency, FDA has to publish the regulation denoting that all the device would meet that type of performance standard.

I give an example, I think one of the few device that the agency has a performance standard, one is a hearing aid. So, they have a standard put out by all the EMTs and they come and say, well, you have to get to a certain type of sensitivity before you qualify as a hearing aid. So, for this type of device, what kind of performance standard you recommend, that will help the agency.

CHAIRMAN SUZUKI: Okay.

Comments from the four yeses.

Dr. Amar?

DR. AMAR: What I think when I suggested performance standard, I think the public needs to know, or have some kind of idea, on in how many cases this device would work, a sense of efficacy, I would say. That's what I meant by performance standard. Is it completely magic, or it works in certain cases, and in how many cases it works.

I think some of the question may come up

from the public to the dentist and say, look, does it work or not?

CHAIRMAN SUZUKI: But, my understanding is, because of May 28, 1976, we can request but not require, is this the case?

MS. SHULMAN: Correct, it was out on the market prior to May 28, 1976, so anything now that's introduced can be found substantially equivalent, and you have to be at least as safe and effective, or, essentially, at least as unsafe and ineffective, as the predicate device.

DR. AMAR: What are the standards for efficacy or effectiveness, that's what I want to know. Safety I know, but efficacy.

MS. SHULMAN: I don't know if there's one standard for effectiveness.

CHAIRMAN SUZUKI: Once again, because it's pre `76 there doesn't have to be a standard.

Dr. Zero?

DR. ZERO: So, in effect, if we have a performance standard that we set for all new devices, in other words, they have to show they are as

effective as a device that's maybe not effective, I mean, how do you design a study to do that? I don't know how to do that.

CHAIRMAN SUZUKI: Dr. Lin?

DR. LIN: Well, actually, the performance standard has a very special meaning in terms of FDA's term, that's become a requirement, that all this type of device have meet those type of standards.

But, I think that from Dr. Amar's comment, it's more a question about whether the effectiveness of this device, but in that case when we have a guidance document we can recommend that the company submit, for example, clinical standard to show that whether the device actually is effective in producing pain relief or anesthesiology, anesthesia, or not, so that we can recommend some clinical standard.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: My expectation is that this device probably has a strong placebo effect, and that if it's done, if you run a placebo-controlled study you will probably see no effect, but that's just a hypothesis, it may not be correct.

So, if you ran a placebo-controlled study to test equivalency, it's going to be as good as the previous device, which you won't be able to break from placebo.

So, I mean, I don't know how to go with this experimentally, because it's -- the only way you can do it is not run a control. If you don't run a control, you can show that they are the same.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Could we address this concern by adding to the labeling that the device may not provide adequate analgesia or anesthesia, and get around the concern that everybody is struggling with?

CHAIRMAN SUZUKI: Eliminate the performance standard and incorporate that statement in the guidance document.

DR. O'BRIEN: I have a comment.

CHAIRMAN SUZUKI: Dr. O'Brien is speaking.

DR. O'BRIEN: Yes. There are many performance standards for devices for use in laboratories, such as devices that operate at a certain voltage, they should be checked that they are

operating at certain voltage. Or, if you have a colorimeter, for example, that measures color, that there's usually a test standard that comes with it, and you first calibrate the device, or see if it's working by its reading in accordance with the reading it should have. I think of that is a performance standard, not in terms of the clinical performance.

CHAIRMAN SUZUKI: Okay.

Ms. Howe?

MS. HOWE: Is that not, in fact, what the standard, the IEC 60601-2-10, provides us, that we are just assuming that they must meet that standard, that we don't have to establish something new here at the Panel?

CHAIRMAN SUZUKI: Okay.

Dr. Lin?

DR. LIN: The IEC standard is a small electrical -- other than actual clinical performance standard.

CHAIRMAN SUZUKI: Thank you.

Other comments, questions?

DR. RUNNER: Marjorie, correct me if I'm

wrong --

CHAIRMAN SUZUKI: This is Dr. Runner speaking.

DR. RUNNER: -- I'm sorry, if the Panel is concerned about effectiveness of the device in general, then the -- and requiring clinical data to support effectiveness, wouldn't that push it over into a different classification?

MS. SHULMAN: Not necessarily, because you can require clinical data in a 510(k), so you can recommend that clinical data be needed to find these devices substantially equivalent.

DR. RUNNER: So that, they could make a recommendation that the guidance document include clinical data to substantiate effectiveness.

MS. SHULMAN: Correct.

CHAIRMAN SUZUKI: Then, perhaps, in light of the further discussion, we can go back, I'd like to request that we go back and revisit at least performance standards as an inclusion.

Would anyone have an objection to that?

Hearing none, I'd like to revote on

performance standards to be included in the recommendation for number seven.

Okay, Dr. Amar?

DR. AMAR: Yes.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: No.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Yes, but that could be the electrical device standard that you mentioned.

MS. SHULMAN: Marjorie Shulman, I just want to clarify something. That would be -- no, I'm sorry, I guess you are right, it could be a performance standard and be required, sorry.

DR. COCHRAN: Isn't that already in the special control, though?

MS. SHULMAN: It is in the special control, but --

DR. COCHRAN: Because you've already got that listed, so it's already there.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: I'm going to change my vote to no, because this is a catch-22.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Yes.

CHAIRMAN SUZUKI: Okay, 3:2 in favor of including performance standard.

MS. SHULMAN: Okay, performance standard.

CHAIRMAN SUZUKI: In addition to guidance document.

MS. SHULMAN: Okay, question number eight we haven't seen yet. If a regulatory performance standard is --

DR. COCHRAN: Excuse me, I have one question. What is the performance standard going to be?

MS. SHULMAN: That performance standard will go out, it will be -- we'll gather the comments from this Panel meeting, and then we'll put one together, and they have to go out for comment to see if anyone has any comments what would have to be in the performance standard, and then it would be final.

CHAIRMAN SUZUKI: Okay.

Dr. Amar?

DR. AMAR: Wouldn't we include clinical

effectiveness, that's what we were talking about, am I correct?

DR. COCHRAN: But, she said that could be included in the 510(k) and the guidance documents. So, I think you are putting something out there for the industry people to meet that is a little bit unnecessary and may not even be achievable.

CHAIRMAN SUZUKI: Okay, we've already voted three times on this, so let's move on.

MS. SHULMAN: Correct, and we have your recommendation, and again, after this is over the proposed regulation will go out and we're going to gather comments, and it may be that that's not included.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: The sense I have of this is right now we are setting up the FDA in, perhaps, an untenable position of developing a performance standard that will fail when being tested as it goes forward, because you will -- if you are going to give -- if you are going to present the performance standard for the industry to meet, and they can't

design -- a study can't be designed, or criteria can't be identified and tested, it doesn't go anywhere. It just ties up the FDA into a circular process, and it just used up the energy of the FDA in a non-productive way.

That's why I changed my vote, that's what I mean by a catch-22.

MS. SHULMAN: Thank you for your comments, but since we have voted three times we will leave that as a recommendation.

CHAIRMAN SUZUKI: Okay.

MS. SHULMAN: Question eight, if a regulatory performance standard is needed to provide reasonable assurance of a Class II or III device, identify the priority. Again, there's no time frames associated with these, low, medium, high.

CHAIRMAN SUZUKI: Okay, beginning first with Dr. Amar, low, medium or high?

DR. AMAR: Low.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Low.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Low.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Low.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Low.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: I'm going to say low, but I think I do so because we don't anticipate these products being hurried into the marketplace, but we assume that by saying low it will be considered at some point.

CHAIRMAN SUZUKI: Okay, Mr. Schechter?

MR. SCHECHTER: Whatever category is below low.

CHAIRMAN SUZUKI: I'll take that as a low.

Dr. Bakland?

DR. BAKLAND: Low.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Low.

CHAIRMAN SUZUKI: Okay, unanimous, low priority.

MS. SHULMAN: Thank you.

Number nine is not applicable because that's for a reclassification, this is a classification.

Number ten, question ten, we can skip.

Question 11, is the prescription device, but then you can add any needed restrictions, use only by persons with specific training or experience, or use only in certain facilities.

CHAIRMAN SUZUKI: So, if we leave it as a prescription device it will be box one.

MS. SHULMAN: Correct.

CHAIRMAN SUZUKI: Okay, beginning first, Dr. Amar?

DR. AMAR: Box 1.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Box 1.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Box 1.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: First box.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: First box..

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: One and two, I think specific training is beyond that of regular dental school instruction.

CHAIRMAN SUZUKI: Okay, Mr. Schechter?

MR. SCHECHTER: First box.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Box 1.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: First box.

CHAIRMAN SUZUKI: Okay, it's unanimous, first box.

MS. SHULMAN: Thank you.

Now we can move on to the supplemental data sheet. Okay, again, if you could put your names on the top, the generic type of device, the Advisory Panel, and question number three, is the device an implant, no.

Number four, the indications for use, you

can say as agreed upon during the Panel meeting, as up on the overhead, or you can add anything that you wish to at this point.

No additional comments?

CHAIRMAN SUZUKI: Any other comments? None.

MS. SHULMAN: Question five, the identification of risk to health by presenting the device. There were two overheads identifying the risks to health and the proposed mitigations. We can add anything else you care to at this time.

DR. ZUNIGA: I don't know if this fits into this category --

CHAIRMAN SUZUKI: This is Dr. Zuniga.

DR. ZUNIGA: -- but I'd be concerned about using this device concerning the adverse events while under general anesthesia.

MS. SHULMAN: Thank you. Most likely we will take those comments and add them on to number nine for the needed labeling restrictions.

If there are no other comments with the identification of the risks to health, then you can

say as presented during the Panel meeting.

Number six, the recommended Advisory classification and priority. The classification is Class II, and again, the priority is high, medium or low.

CHAIRMAN SUZUKI: Okay. I'll poll the Panel, beginning first with Dr. Amar, low, medium or high.

DR. AMAR: Low.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Low.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Low.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Low.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Low.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Low.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Low.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Low.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Low.

CHAIRMAN SUZUKI: Unanimous, low.

MS. SHULMAN: Thank you.

Number seven we may skip, because it is not an implant or life-sustaining or life-supporting.

Number eight, the summary of clinical experience or judgment upon which the classification recommendation is based, we can say as presented during the Panel meeting, or you can add anything else you wish to at this time.

No other comments.

Number nine, the identification of any needed restrictions for the use of the device, it is a prescription device, that will be a restriction, and we do have a comment, the Panel comments about the additional needed labeling. If there are anymore.

CHAIRMAN SUZUKI: Any comments? None.

MS. SHULMAN: Thank you.

Number ten we will skip.

Number 11, if device is recommended for Class II recommend whether the Panel should exempt it from pre-market notification.

CHAIRMAN SUZUKI: Okay, I'll begin with Dr. Amar, exempt or non-exempt?

DR. AMAR: Not exempt.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: Not exempt.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: Not exempt.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: Not exempt.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: Not exempt.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: Not exempt.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: Not exempt.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: Not exempt.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: Not exempt.

CHAIRMAN SUZUKI: Unanimous, not exempt.

MS. SHULMAN: Thank you.

And, besides the ones listed in question 12, besides these standards listed in the presentation, any other existing ones that you all know of?

CHAIRMAN SUZUKI: Any questions, discussion? No.

MS. SHULMAN: Okay.

Now, if you can please vote on the form as filled out as a Class II device, not 510(k) exempt, subject to pre-market notification, subject to the guidance document and performance standards.

CHAIRMAN SUZUKI: Okay, I will poll in order again, in favor or opposed.

Dr. Amar?

DR. AMAR: In favor.

CHAIRMAN SUZUKI: Dr. Cochran?

DR. COCHRAN: In favor.

CHAIRMAN SUZUKI: Dr. O'Brien?

DR. O'BRIEN: In favor.

CHAIRMAN SUZUKI: Dr. Zero?

DR. ZERO: In favor.

CHAIRMAN SUZUKI: Dr. Zuniga?

DR. ZUNIGA: In favor.

CHAIRMAN SUZUKI: Representatives.

Ms. Howe?

MS. HOWE: In favor.

CHAIRMAN SUZUKI: Mr. Schechter?

MR. SCHECHTER: In favor.

CHAIRMAN SUZUKI: Consultants.

Dr. Bakland?

DR. BAKLAND: In favor.

CHAIRMAN SUZUKI: Dr. Demko?

DR. DEMKO: In favor.

CHAIRMAN SUZUKI: Unanimous, in favor.

MS. SHULMAN: Thank you very much.

CHAIRMAN SUZUKI: Okay, we have now reached the end of today's agenda. We'll reconvene tomorrow morning at 8:00 a.m., and at that time we'll have discussions on proposed classifications of root canal

cleanser, root apex locator, and dental mouth guards.

I call for adjournment.

(Whereupon, the above-entitled matter was concluded at 2:34 p.m., to reconvene tomorrow morning at 8:00 a.m.)