special control guidance document to support the classification of the low energy ultrasound wound cleaner into class II (special controls). This device is intended for the cleaning and maintenance debridement of wounds. On April 29, 2004, Celleration, Inc., submitted a petition requesting classification of the Celleration MIST Therapy System™ under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the low energy ultrasound wound cleaner into class II (special controls) under section 513(f)(2) of the act. This guidance document will serve as the special control for the low energy ultrasound wound cleaner device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation in § 10.115. The guidance represents the agency's current thinking on the low energy ultrasound wound cleaner for the cleaning and maintenance debridement of wounds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1302 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 5, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–22069 Filed 11–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DEPARTMENT OF AGRICULTURE

Food Safety Inspection Service

[Docket No. 05–013N]

Meeting To Discuss Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry

AGENCIES: Food and Drug Administration, HHS; Food Safety Inspection Service, USDA.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in the Department of Health and Human Services, and the Food Safety Inspection Service (FSIS), in the United States Department of Agriculture (USDA), are jointly announcing a public meeting to discuss and solicit information on an approach for providing consistency and predictability with respect to which of the two agencies should have jurisdiction over certain types of food products that contain meat and poultry as ingredients, as well as the opening of a joint agency docket to receive written comments. This notice outlines that approach and solicits comments on it and on the specific questions asked in section II below.

DATES: The public meeting will be held on December 15, 2005, from 10 a.m. to 4 p.m.

ADDRESSES: The public meeting will be held at the Donald E. Stephens Convention Center, 5555 North River Road, Rosemont, IL 60018, 847–692–0222.

You may submit comments, identified with Docket No. 05–013N, by any of the following methods:

- Electronic mail:

FSIS: FSIS *regulationsComments@fsis.usda.gov*. Follow the instructions for submitting comments on the Agency's Web site.

• FAX:
FSIS: 202–690–0486.
• Mail/Hand delivery/Courier (For paper, disk, or CD–ROM submissions):
FSIS: Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250
FDA: Division of Dockets Management, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.
Instructions: All submissions received must include Docket No. 05–013N. All comments received will be posted without change to: (FSIS) *http://www.fsis.usda.gov/regulations_&_policies/2005_Notices_Index/index.asp.;* (FDA) *http://www.fda.gov/dockets/ecomments.*
Submissions received must include the Agency name and Docket No. 05–013N. All comments submitted will be available for public inspection in the Agencies' Docket Offices and on the Agencies' Web sites.

FOR FURTHER INFORMATION CONTACT: For general questions about the meeting contact Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1584, FAX: 301–436–2605, e-mail: *marion.allen@fda.hhs.gov.*
Please see Section III. Registration, for information on how to register for the Public Meeting.
For technical questions about the subject of the meeting: FDA: Karen Carson, Director, Executive Operations Staff (EOS), Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1664, FAX: 301–436–2668, e-mail: *kcarson@cfsan.fda.gov.*
FSIS: Philip S. Derfler, Assistant Administrator, Office of Policy, Program, and Employee Development (OPPED), Food Safety Inspection Service, 1400 Independence Ave., SW., Suite 350–E Whitten Building, Washington, DC 20250, (202) 720–2709, FAX: (202) 720–2025, e-mail: *Philip.Derfler@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION

I. Background

Both FSIS and FDA have regulatory authority over the food supply. Under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA), FSIS has authority over all meat and poultry products and processed egg products. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA has authority over all foods not under FSIS' jurisdiction (e.g., dairy, bread and other grain products, vegetables and other produce, and other products such as seafood).

Over the years, FSIS has made jurisdictional decisions based on various factors, including the amount of meat or poultry in the product; whether the product is represented as a meat or poultry product (that is, whether a term that refers to meat or poultry is used on labeling); and whether the product is perceived by consumers as a product of the meat or poultry industries. With regard to the consumer perception factor, FSIS has made decisions on a case-by-case basis, mostly in response to situations involving compliance and enforcement. Although this case-by-case approach resulted in decisions that made sense at the time, a recent review by the agencies highlighted that some decisions do not appear to be fully consistent with other product decisions and that the reasoning behind various determinations were not fully articulated. For example, the reasoning for deciding that a ''bagel dog'' (a product composed of a hotdog wrapped in bagel dough which is then baked) was not a meat product was conveyed in a letter from FSIS to a trade association in 1979 (Letter from Irwin Fried, Acting Director, Meat and Poultry Standards and Labeling Division, to Pacific Coast Meat Association, January 8, 1979). The letter stated that the product was viewed as a ''closed-face'' sandwich and, thus, was not under FSIS jurisdiction. However, the Agency did not explain why such products were viewed as closed-face sandwiches or the importance of this view. Moreover, the letter did not explain why bagel dogs were different than other products that were similarly configured, e.g., ''corn dogs'' and ''sausage turnovers,'' that were, and continue to be, manufactured under FSIS jurisdiction.

Confusion persists about the reasoning used with respect to various decisions about which agency has jurisdiction over certain food products containing meat and poultry. For example, manufacturers have wanted to change the original formulations of products that were the subject of jurisdictional decisions, e.g., bagel dogs and pepperoni rolls.[1] By adding new ingredients, e.g., adding cheese and other meat and poultry ingredients, manufacturers have created ''bagel dogs with cheese'' and ''pepperoni, ham, and cheese rolls.'' Although the manufacturers requested that FSIS categorize these new products like their predecessors, FSIS has denied these kinds of requests because, without a clear rationale supporting the original decisions, FSIS believed that confusion would be compounded further by perpetuating the rationale contained in the original decision.

In other situations, manufacturers have expressed confusion about the classification of new versions of traditional food products because products with similar composition are produced under the jurisdiction of a different agency. For example, FSIS decided decades ago that closed-face sandwiches made with meat ingredients were not meat products and, thus, were products under FDA's regulatory jurisdiction. Recently, manufacturers of ''wrap-type sandwiches with meat'' have argued that wraps are similar enough to closed-face sandwiches such that wraps should fall under FDA's jurisdiction. There are wrap-like products, (meat burritos, meat egg rolls, and meat tamales), which FSIS has categorized as meat products and which are more similar in composition to the wrap-sandwich. Because wrap-type sandwiches are new to the market and the historic decision about closed-face sandwiches did not include them, FSIS concluded that wrap-type sandwiches are meat products.

These and other circumstances led FSIS and FDA to conduct an in-depth examination of the historic decisions about regulatory jurisdiction made by FSIS. An FSIS–FDA working group met to explore the issue and to develop an approach for making sound, clear, and transparent decisions about product categorization and agency jurisdiction.

As a result of the working group's findings, the agencies concluded that a clearer approach to determining jurisdiction is possible. This approach involves considering the contribution of the meat or poultry ingredients to the identity of the food. In some cases, the meat or poultry ingredients are distinctive and significantly contribute to a food's basic nature by characterizing the food. In other cases, the meat or poultry ingredients are used in such a way that they do not contribute to the product's basic nature because they are not easily distinguished and are used to simply add flavor. The agencies recognized, however, that application of this approach could lead to changes in jurisdiction for certain foods and categories of foods and thus felt that it was important to present this approach

[1] Pepperoni rolls are a product that was the subject of a FSIS jurisdictional decision in 1986. They are a product that is composed of pieces of pepperoni that are distributed in bread dough which is then baked.

for public comment before taking steps to implement any changes.

A change in jurisdiction may be in order for the products and product categories described below. Bagel dogs, closed-face meat and poultry-containing sandwiches, and natural casings, regulation of which would move from FDA to FSIS jurisdiction, are products or product categories characterized by the meat or poultry ingredients that they contain. Further, these products are identified by terms that refer to the meat and poultry ingredients, reflecting the contribution of the meat and poultry components. In contrast, meat and poultry components are added to other products/product categories, such as bread/rolls/buns, cheese products, flavors, pizzas, and salad dressings, to add flavor but not to alter the character of the products. Such products would move from FSIS to FDA jurisdiction.

Bagel Dogs

Bagel dogs were the subject of a jurisdiction decision that FSIS made almost 20 years ago. The decision made at that time was that a product composed of a cooked hotdog wrapped in bagel dough, which is baked, is not itself a meat product. Bagel dogs thus fell under FDA jurisdiction. Bagel dogs, however, are similar to other meat-filled, dough-encased or wrapped products—such as corn dogs and sausage turnovers—which have historically been under FSIS jurisdiction. These products are composed of a meat or poultry filling that is encased or wrapped in dough or crust which provides a convenient container for the ingredients for hand-held eating. The meat and poultry components characterize the products and the characteristics of the meat/poultry ingredients are not changed by the bread, dough, or crust around it. Because the agencies have not been able to distinguish bagel dogs from corn dogs and similar products, the agencies are considering changing the jurisdiction of bagel dogs from FDA to FSIS.

Natural Casings

At least as far back as the 1950's, USDA made a jurisdictional decision that natural casings, which are used for sausages and other stuffed and formed meat and poultry products, are not meat byproducts because they serve as a container or packaging for the meat or poultry put in the casing. As a result, natural casings have been under FDA jurisdiction. But natural casings originate from meat byproducts, (specifically, from parts of livestock digestive tracts) which are under FSIS jurisdiction. The process of sanitizing and sizing the livestock materials does not change them to the degree that their basic identity as meat byproducts such as bungs, stomachs, intestines is changed. Therefore, the agencies are considering changing the jurisdiction of this category of products from FDA to FSIS.

Closed-Face Sandwiches Made With Meat or Poultry

According to FSIS policy going back to the 1930's, closed-face sandwiches (products containing at least 35% cooked meat and poultry products, by weight, placed between 2 slices of bread, biscuit, or bun, which are less than 50 percent of the weight of the product) were not meat or poultry products because consumers viewed them as products primarily prepared in local food service establishments (FSIS Food Standards and Labeling Policy Book, 2003). Today, however, sandwiches containing meat or poultry components in their majority are made in manufacturing facilities and are shipped in interstate commerce. Moreover, in determining regulatory jurisdiction, it makes sense to consider the contribution of the meat ingredient to the product.

Meat and poultry sandwiches are generally consumed for the distinctive meat and poultry ingredients, not for the bread that surrounds them. In other words, it is the meat or poultry ingredients that characterize the sandwich, which is not changed by the bread, biscuit, or bun between which they are placed. Furthermore, sandwiches are similar to the other meat- or poultry-filled, dough-encased or wrapped products that were discussed earlier have historically been under FSIS jurisdiction. Therefore, the agencies are considering changing the jurisdiction of these products from FDA to FSIS.

Cheese and Cheese Products (Including Cheese Dips) Made With Less Than 50 Percent Meat or Poultry

Products that meet the standards of identity in 21 CFR Part 133 for Cheeses and Cheese Products (i.e., pasteurized blended cheese, process cheese, cheese food, cheese spread) are not considered meat or poultry products. The standard of identity for such products allows for optional ingredients, including meat ingredients. Based on this standard, FSIS decided many years ago that some cheese products such as cheese balls and cheese logs that include small pieces of inspected and passed ready-to-eat meat (e.g., dried sausage or cooked bacon) at less than 50 percent of their formulation (by weight) were not meat products and should fall under FDA jurisdiction. However, this FSIS decision has never been extended to all cheese and cheese products or to those that contain poultry. The agencies have considered this decision and, as a result, the agencies are suggesting that the addition of less than 50 percent inspected and passed ready-to-eat meat or poultry ingredients does not change the characteristics of cheese or cheese products (whether or not the product is covered by an FDA standard of identity) because, at less than 50 percent of the weight of the product, the meat or poultry added is used for flavoring effect. Therefore, the agencies are considering changing the jurisdiction of these products from FSIS to FDA.

Bread, Rolls, and Buns Made With Less Than 50 Percent Meat or Poultry

The jurisdiction of pepperoni rolls is an example of a bread-based product that has caused confusion since a decision was made in 1986 by FSIS that such a product is not a meat product, and is, therefore, under FDA's jurisdiction (Letter from Margaret O. Glavin to State of West Virginia, Department of Agriculture, January 8, 1986). The original decision was made for a product that was composed of small pieces of pepperoni that were dispersed throughout bread dough and baked. At the time, the product was prepared in such a way that it was viewed by FSIS as being a product of the bakery industry. More recently, FSIS has viewed products with variations of the original formulation (e.g., pepperoni, ham, and cheese rolls) as meat and poultry products because these products are not consistent with the formulation of the product for which the original jurisdictional decision was made.

In reviewing the decision about pepperoni rolls and the other decisions made about bread-based products over the years, the agencies considered the standards of identity for bakery products in 21 CFR Part 136, Bakery Products. Such products, which include bread, rolls, and buns, are foods produced by baking dough made from farinaceous ingredients into which optional ingredients may be dispersed for flavor. Meat and poultry are not permitted optional ingredients in the standards for breads, rolls, and buns in Part 136. Therefore, these foods to which meat or poultry are added are non-standardized foods. The agencies believe that meat and poultry ingredients can be added to any bakery product for flavoring.

The agencies are now considering changing the jurisdiction from FSIS to

FDA of the original pepperoni roll products, as well as those foods with variations of this original formulation. Such products would be prepared with less than 50 percent inspected and passed ready-to-eat meat or poultry, dispersed throughout the dough for a flavoring effect. (As a general matter, most products containing meat or poultry are composed of well below or well above 50 percent meat or poultry by weight.)

Dried Poultry Soup Mixes

Dried meat soup mixes, regardless of the amount of meat they contain, are currently under FDA jurisdiction based on a FSIS decision made decades ago, which is reflected in the FSIS Food Standards and Labeling Policy Book (2003). Dried poultry soup mixes, however, have historically been considered to be poultry products (FSIS Food Standards and Labeling Policy Book). This has been a point of disparity and confusion. Based on FSIS' experience in reviewing product formulations, dried soup mixes with meat or poultry are composed of less than 50 percent inspected and passed dried/powdered meat/poultry (by weight). The meat and poultry components used to prepare these products are not in a form that is recognized as ''meat'' or ''poultry'' and are used at low levels for seasoning or flavoring effects. For this reason and for the sake of parity, the agencies are considering changing the jurisdiction of dried poultry soup mixes from FSIS to FDA.

Flavor Bases/Flavors

Flavor bases and reaction/process flavors are produced by rigorous heating (e.g., 100 °C or higher) and by chemical processes (e.g., hydrolysis/enzymolysis). Such products that are prepared with inspected and passed meat or poultry ingredients are in a powder, slurry, or paste form. They are used in other products for a flavoring effect, not for their contribution to the meat or poultry content of the food products. Furthermore, such products are typically sold for use within the food industry, not for use by household consumers. Therefore, the agencies are considering changing the jurisdiction of this category of products from FSIS to FDA.

Pizzas With Meat or Poultry

In 2003, FSIS eliminated the standard of identity for traditional pizzas with meat or poultry (68 FR 44859, July 31, 2003). Thus, traditional pizzas composed of sauce, cheese, and inspected and passed meat or poultry toppings on a layered crust need only contain 2 percent meat or poultry by weight to be under FSIS jurisdiction. However, the base onto which toppings are placed represents the majority of the product, and meat or poultry ingredients may be among any number of toppings used for flavoring purposes. While the meat or poultry toppings provide flavoring to the finished food, they do not change the character of the food. Because non-meat/poultry pizzas have always been under FDA's jurisdiction, and the meat or poultry ingredients are generally used to provide flavor, the agencies are considering changing the jurisdiction of these products from FSIS to FDA.

Salad Dressings Made With Less Than 50 Percent Meat or Poultry

Over the years, FSIS has made jurisdictional decisions that salad dressing products made with cooked meat ingredients (e.g., cooked bacon) are not meat products. The basis for the decisions was that such products were consistent with the standards of identity for ''dressings'' in 21 CFR Part 169, Food Dressings and Flavorings. Although the standards do not list meat ingredients as optional ingredients, the meat ingredients were not considered to characterize the dressings as meat products, nor were they considered to characterize non-standardized dressings, such as vinaigrettes. As optional ingredients, the meat or poultry ingredients are intended to provide flavor and do not contribute to the characterization of the products as salad dressings. There has, however, been occasional confusion regarding under which agency would regulate the product. The agencies therefore are contemplating making clear that salad dressings that contain less than 50 percent inspected and passed, ready-to-eat meat or poultry ingredients by weight (e.g., cooked bacon), are not meat or poultry products and are under FDA jurisdiction.

The agencies recognize that these jurisdictional changes would affect firms and establishments, as well as the agencies themselves. It is unlikely that, in most cases, affected firms or establishments would have to overhaul production facilities or processing operations, significantly alter marketing approaches, or change product formulations to take actions to meet the regulatory requirements of one or the other agency. It is likely, however, that with the suggested changes in jurisdiction, there will be additional administrative, inspection, and labeling requirements. For example, firms moving to FSIS jurisdiction would need to: receive grants of inspection; develop and implement hazard analysis and critical control point (HACCP) plans, sanitation standard operating procedures (SSOPs), and pathogen control and other laboratory testing procedures; develop and implement systems of recordkeeping; and obtain product label approvals.

II. Public Meeting

FSIS and FDA are holding this public meeting in order to gain public input on the ideas set out in this notice and on the impact of the changes discussed herein. In order to benefit from this public meeting, the agencies are seeking input on a number of questions, including:

- Is the approach that is suggested by the agencies a reasonable one? If not, why not?
- Are there other food products or product categories that have been the subject of historical regulatory jurisdictional decisions by FSIS, which were based on a consumer perception factor, that should be considered by the agencies?
- How many firms or establishments would be affected for each product and product category? What is the volume of production for each product or product category?
- Would there be modifications in equipment, facility design, labeling, recordkeeping, or processing and reporting responsibilities that are needed in order for current operations to continue making the products that are the subject of the suggested changes, and what are they?
- What would the administrative, operational, marketing, and labeling costs be associated with changes in product jurisdiction?
- What would be a reasonable process and time frame within which to implement any changes in jurisdiction?
- What would be consumers' views of the subject products under the suggested approach? More particularly, what effect would changing regulatory jurisdiction have on consumers' perceptions of the subject products? For example, what would consumers' reaction be to the fact that dried chicken soup mix is regulated by FDA?
- What effects would there be, if any, on the way the subject products are marketed?

The agencies seek as much information as possible about the impact of any changes in jurisdiction.

III. Registration

Please submit your registration information (including name, title, firm name, address, telephone number, e-

mail address, and fax number) at least 5 workdays before the public meeting date. We encourage you to register online at *http://www.cfsan.fda.gov/-comm/register.html.* or to fax your registration directly to Marion V. Allen at 301–436–2605. We will accept registrations onsite. Space is limited and registration will be closed when maximum seating capacity is reached (250 people). If you need special accommodations due to a disability, please notify Marion V. Allen at least 7 workdays in advance.

We encourage individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record. If you would like to make oral comments at the meeting, please specify your interest in speaking when you register. The amount of time for each oral presentation will be limited to 5 minutes.

IV. Transcripts

A transcript will be made of the proceedings of the meeting. You may request a copy of the meeting transcript in writing approximately 30 working days after the public meeting at a cost of 10 cents per page from:

FDA: FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857; or

FSIS: FSIS, Freedom of Information Office, USDA, 1400 Independence Ave., SW., Room 1140 South Building, Washington, DC 20250.

The transcript of the public meeting and all comments submitted will be available for public examination at the Agencies' Docket Offices (see **ADDRESSES** for locations and hours).

V. Comments

In addition to presenting oral comments at the public meeting, interested persons may submit written or electronic comments on the subject of this meeting and **Federal Register** notice to a joint agency docket housed at FSIS.

FSIS: Submit comments by any of the following methods: Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items.

Comments are to be identified by the Docket No. 05–013N. All comments submitted in response to this notice will be available for public inspection in the Agencies' Docket offices and web sites. [See **ADDRESSES** section for location and hours].

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2005_Notices_Index/index.asp.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS web page. Through Listserv and the web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices.

Customers can add or delete subscriptions themselves and have the option to password protect their account.

Done in Washington DC on: November 2, 2005.

Jeffrey E. Shuren,

Assistant Commissioner for Policy, Food and Drug Administration.

Sean Altekruse,

Deputy Executive Associate Administrator, OPPED, Food Safety Inspection Service.

[FR Doc. 05–22123 Filed 11–3–05; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Women's Health Initiative Observational Study

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, Office of the Director, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Women's Health Initiative (WHI) Observational Study. *Type of Information Collection Request:* Revision OMB #0925–0414 Exp: 04/06. *Need for Use of Information Collection:* This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Continuation of follow-up years for ascertainment of medical history update forms will provide essential data for outcomes assessment for this population of aging women. *Frequency of Response:* On occasion. *Affected Public:* Individuals and physicians. *Type of Respondents:* Women, next-of-kin, and physician's office staff. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
OS Participants	85,786	1	.21	18,195