FACILITY AUTOMATION MANAGEMENT ENGINEERING (FAME) SYSTEMS
33 Hoffman Avenue Lake Hiawatha, NJ 07034-1922

Tuesday, 28 September 2004

Documents Management Branch [**HFA-305**]
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 04N-0214

FORMAL SIGNIFICANT ADVERSE COMMENTS ON:

"Public Information Regulations, Direct Final Rule"

Pursuant to a "request for comment" in ***FEDERAL REGISTER,*** **Vol. 69**, **No. 1708**, pp 53615 – 53616.

BACKGROUND

After an initial reading and a rereading of the FDA's proposed "**Public Information Regulations, Direct Final Rule**, and a thoughtful reading of the notice soliciting comment in the Federal Register, FAME Systems offers the comments that follow.

To clearly separate **FAME Systems'** review statements from the FDA's statements, **FAME Systems'** comments are in an **Arial** or ***italicized Arial*** font and the basis statements are in a **Times New Roman** or other font like that used by the FDA.

When either a binding regulation or a statute is quoted, the text is in a **Lydian** font.

When other recognized sources are quoted, a **Perpetua** font is used.

Should anyone who reads these comments find that their guidance is at odds with sound science or the applicable statutes and/or regulations, or that additional clarification is needed in a given area, then, in addition to providing the sound science or rationale that refutes the comment text provided, or his or her clarifying comments to the public docket, he or she is asked to e-mail **drking@dr-king.com** a copy of that sound science, rationale, and/or commentary.

Respectfully,

Dr. King

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This FDA notice begins by stating the following:

"SUMMARY: The Food and Drug Administration (FDA) is amending its public information regulations to implement more comprehensively the exemptions contained in the Freedom of Information Act (FOIA). This action incorporates exemptions one, two, and three of FOIA into FDA's public information regulations. Exemption one applies to information that is classified in the interest of national defense or foreign policy. Exemption two applies to records that are related solely to an agency's internal personnel rules and practices. Exemption three incorporates the various nondisclosure provisions that are contained in other Federal statutes. Elsewhere in this issue of the Federal Register, FDA is publishing a companion proposed rule, under the agency's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES: The rule is effective January 17, 2005. Submit written or electronic comments by November 16, 2004. If FDA receives no significant adverse comments by the specified comment period, the agency will publish a document in the Federal Register confirming the effective date of this direct final rule. If the agency receives any significant adverse comments during the specified comment period, FDA intends to withdraw this direct final rule before its effective date by publication of a document in the Federal Register."

Based on the Food and Drug Administration's (FDA's) introductory remarks, this commenter is compelled to state, from the outset, that the formal comments that follow constitute "**SIGNIFICANT ADVERSE COMMENTS.**"

At a time when Congressional scrutiny has clearly established that the FDA is openly putting protecting the interests of the pharmaceutical industry above public health, it is, or should be, clear that the activities of the FDA need to be, if anything, opened up to the public

[For example, including, but not limited to,

- Continuing to allow drugs containing poisonous levels of mercury to remain on the market, allowing the presence of mercury in certain drugs to be concealed from and/or misrepresented to the public, permitting the manufacturers to use duplicitous "preservative free" labeling terminology (**note:** instead of requiring **ALL** drugs containing mercury to be labeled with the maximum allowable level that any released lot of a given drug formulation can contain using the terminology "contains not more than "NN,NNN.N" nanograms of mercury per dose followed by, in parentheses, the actually "nanogram/dose" level [a nanogram, ng; is 10^{-9} gram], UNLESS the maximum level is not more than 1.0 nanograms of mercury per dose [in which case, the drug container should be labeled "trace mercury/dose"]) on vaccines that still contain mercury at levels that have NOT been proven NOT to be neurotoxic to those in the population that are "susceptible" to mercury poisoning,
- Refusing to control the equal mutagenic drug Accutane® in the same manner as the equally mutagenic drug Thalidomide®, failing to require the manufacturer of Accutane to similarly restrict the product sold to Mexico based on the documented off-label use and advertising that encourages those who cannot legally get the drug in the United States to simply cross the border and purchase it there because, though "expensive," it is readily available in Mexico,

- Refusing to prohibit the prescribing of antidepressants, other than Prozac, to young children and adolescents when the evidence of harm was clear and overwhelming and, instead, attempting to silence those medical experts in the FDA who had established the validity of the problem,
- Recently allowing manufacturers not to recall batches of vaccines contaminated with particulates even though these were knowingly distributed in violation of the Federal Food, Drug, and Cosmetic Act's prohibitions for so doing (**21 U.S.C. 331(a)**),
- Refusing to sanction pharmaceutical manufacturers who knowingly violate the CGMP minimums set forth in **21 CFR § 211.84**, **21 CFR § 211.110**, **21 CFR § 211.160**, and **21 § CFR 211.165** with respect to, among other things, *representative sampling*, *each batch at each stage uniformity assessment for each critical factor* that may adversely affect in-process and product quality, *scientifically sound and appropriate batch specifications*, and the use scientifically sound and appropriate statistical quality control for batch acceptance for release,

The FDA's document continues by providing the following information:

"SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending its public information regulations to incorporate exemptions one, two, and three of the FOIA (5 U.S.C. 552). FOIA provides that all Federal agency records shall be made available to the public upon request, except to the extent those records are protected from public disclosure by one of nine exemptions (5 U.S.C. 552(b)) or one of three special law enforcement record exclusions (5 U.S.C. 552(c)). FDA originally issued its public information regulations implementing FOIA in 1974. As noted at the time, FDA's 1974 regulations explicitly addressed four of the nine FOIA exemptions that were then perceived to be of particular importance to the agency, those relating to trade secrets, internal memoranda, personal privacy, and investigatory files (39 FR 44602, December 24, 1974). FDA now finds it necessary to address exemption one (5 U.S.C. 552(b)(1)), given the President's designation of the Secretary of Health and Human Services to classify information under Executive Order 12958 (66 FR 64347, December 12, 2001). Because exemption two (5 U.S.C. 552(b)(2)) applies to, among other types of records, internal matters whose disclosure would risk circumvention of a legal requirement, this exemption is of fundamental importance to homeland security in light of recent terrorism events and heightened security awareness. In addition, FDA now finds that exemption three (5 U.S.C. 552(b)(3)), which incorporates the various nondisclosure provisions that are contained in other Federal statutes, is becoming increasingly important to the agency. As such, FDA is amending, by direct final rule, subpart D of its public information regulations in 21 CFR part 20 to incorporate these three exemptions."

While the President may have designated "the Secretary of Health and Human Services to classify information under Executive Order 12958 (66 FR 64347, December 12, 2001)," that designation, as the FDA's filing indicates, in no way

grants the Secretary any *a priori* rights to act in any manner that is clearly at odds with any binding regulation or statute.

Further, given the recent increases in the body of evidence that the FDA is knowingly operating outside of its legal statutory authorities and, quite literally, knowingly aiding in the obstruction of the Agency's mandate to protect the health of the public that have been uncovered through FOIA requests under the current rules, it is easy to see why the FDA is anxious to change those rules in a manner that reduces transparency and public access.

However, this commenter would strongly counsel the Agency to resist this "hide the evidence" impulse if it wishes to preserve the limited level of public trust that the public still has in the Agency and its actions.

This commenter provides this counsel because "there is nothing covered, that shall not be revealed; and hid that shall not be known" (Matthew 10:26)."

"II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule amends the agency's public information regulations by incorporation of exemptions one, two, and three of FOIA, which have become increasingly relevant to FDA and its records. Because these exemptions are already contained in FOIA, this action should be noncontroversial, and the agency does not anticipate receiving any significant adverse comments on this rule."

Contrary to the Agency's expectation, since:

- FOIA only provides for, but does NOT mandate, the adoption of, the aforementioned exemptions,
- There is an ever-increasing body of evidence of recent and ongoing Agency wrongdoing that has been uncovered and elucidated by documents that FOIA requests (which these proposed amendments would most certainly block) have provided
- The very reason for FOIA was to ensure that there was sufficient public access (transparency) concerning government actions, and
- The Agency has been found, and seems, to be continually knowingly operating outside of its lawful boundaries (by, for example,
  a. Knowingly participating in illegal meetings (ones that were supposed to be open to the public but were not [e.g., the 1999 Lister Hill and 2000 Simpsonwood meetings]) or where the cost-to-attend bars the general public from attending (a prevailing and increasing trend within much of the Agency – namely, holding that third-party conferences between the industry and the Agency are "public meetings" even though the cost to the "public" to attend such meetings is in the hundreds or thousands of dollars and in spite of the complaints by the public that the sponsors of such meetings have acted to discourage certain members of the "public" from attending, and

b. Knowingly and willfully illegally ignoring:
   - The ***clear*** binding statutory requirements [e.g., not less than a bi-annual inspection of all drug and device facilities, failing to prosecute all those firms who have a knowing ***pattern*** of conduct that ***continually*** introduces adulterated and misbranded drugs into commerce as per **21 U.S.C. § 333** and **21 U.S.C. §§ 335** through **335c**, because any reasonable person would find that such ongoing knowing patterns of conduct clearly fall outside of the discretion granted to the Secretary by **21 U.S.C. 336**, and failing to mandate the removal of all forms of the cumulative poison mercury from vaccines as **42 U.S.C. § 300aa-27** clearly directs since said removals would most certainly safen said vaccines with respect to their contributing to the mercury poisoning of those individuals with developing brains who continue to receive vaccines containing neurotoxic levels of mercury (> 10^{-10} M; 0.0001 micrograms per milliliter [**see:** Christopher C. W Leong, Naweed I. Syed and Fritz L. Lorscheider, "Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury," ***NeuroReport***, **12**(4) pages 733-737 (2001)] containing vaccines] and
   - The ***clear*** binding regulatory requirements (*e.g.*, the multiple representative-sample sampling requirements set forth in **21 CFR § 211**, the clear each-batch in-process control requirements set forth in **21 CFR § 211.110**, and the clear statistical quality control criteria requirements set forth in **21 CFR § 211.165(d)**, to again name a few),

the Agency is, at best, somewhat naive with respect to its assessment that "this action should be noncontroversial", as this commenter's remarks clearly establish, the Agency is most certainly receiving "significant adverse comments on this rule."

"If FDA does not receive significant adverse comments during the specified comment period, the agency will publish a document in the Federal Register confirming the effective date of this direct final rule (see DATES). A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change."

As this commenter's prior remarks and those made subsequently clearly demonstrate, this commenter's remarks in part and/or in whole are clearly a "significant adverse comments" as the Agency has defined that term in this notice.

"A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change."

In making his regulation specific recommendations vis-à-vis the FDA's proposal, this commenter both accepts the Agency's position and, to the extent possible, has complied therewith, to the best of this commenter's ability.

"If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the Federal Register withdrawing this direct final rule."

Hopefully, after receiving this commenter's remarks, the agency will, after reviewing all of the significant adverse comments that it receives, "publish a document of significant adverse comment in the Federal Register withdrawing this direct final rule" and also withdraw the "companion proposed rule" on the grounds that no rule change should be considered UNTIL the Agency can be reformed into an Agency that CLEARLY: **a)** is, itself, law abiding, **b)** puts public health ahead of the interests of all of the industries it regulates, and **c)** prosecutes those individuals and firms who have been operating outside of the bounds the clear minimums established by current good manufacturing practice (CGMP) as that term is set forth in **21 U.S.C. 351(a)(2)(B)**.

"Elsewhere in this issue of the Federal Register, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the proposed rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to an amendment, paragraph, or section of this direct final rule and that provision may be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on the direct final rule procedures may be found in a guidance document published in the Federal Register of November 21, 1997 (62 FR 62466)."

As discussed in the preceding section, the agency should, after reviewing all of the significant adverse comments that it receives, "publish a document of significant adverse comment in the Federal Register withdrawing this direct final rule" and also withdraw the "companion proposed rule" on the grounds that no rule change should be considered.

This commenter finds that the FDA and other governmental health agencies currently seem to be moving, *under the guise of the Patriot Act and Presidential Executive Orders*, to make it much more difficult for the public to discover "sensitive" information under FOIA in the future. After carefully reading the language in the docket item labeled **NPR-01**, "Public Information Regulations; Companion Document to Direct Final Rule," this commenter is

compelled to strenuously object to all of the changes being made, especially the seemingly innocuous, proposed **21 CFR § 20.67**, that states,

"Sec. 20.67 Records exempted by other statutes.

Records or information may be withheld from public disclosure if a statute specifically allows the Food and Drug Administration (FDA) to withhold them. FDA may use another statute to justify withholding records and information only if it absolutely prohibits disclosure, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld."

At a minimum, this section should be changed to read,

"Sec. 20.67 Records exempted by other statutes.

Records or information may be withheld from public disclosure **only** if a statute specifically ~~allows~~ **requires** the Food and Drug Administration (FDA) to withhold them. FDA may use another statute to justify withholding records and information only if it absolutely prohibits disclosure~~, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld~~."

The overarching intent of the Freedom of Information Act (FOIA) is to ensure public access and transparency in the all of the agencies of the government. The draft language clearly ignores this intent and tramples on the very essence of FOIA. Moreover, the language in the regulation is unnecessarily restrictive and would serve to further undermine the public's trust in the FDA. For all of the preceding reasons, the proposed language should be modified as suggested.

Similarly, the proposed **21 CFR § 20.66** that states:

"Sec. 20.66 Internal personnel rules and practices.

Records or information may be withheld from public disclosure if they are related solely to the internal personnel rules and practices of the Food and Drug Administration (FDA). Under this exemption, FDA may withhold records or information about routine internal agency practices and procedures. Under this exemption, the agency may also withhold internal records whose release would help some persons circumvent the law."

should be changed to read,

"Sec. 20.66 Internal personnel rules and practices.

Records or information may be withheld from public disclosure if they are related solely to the internal personnel rules ~~and practices~~ of the Food and Drug Administration (FDA). Under this exemption, FDA may **only** withhold records or information about routine internal agency **personnel** practices and **personnel** procedures **except that the Agency may not withhold such from a requesting person who is or was subject to such personnel practices and personnel procedures and who is seeking redress for a wrongful evaluation, threat of termination or termination**. ~~Under this exemption, the agency may also withhold internal records whose release would help some persons circumvent the law~~."

Again, the overarching intent of the Freedom of Information Act (FOIA) is to ensure public access and transparency in the all of the agencies of the government.

The draft language clearly ignores this intent and tramples on the very essence of FOIA.

Further, the language in the regulation is unnecessarily restrictive and would serve to further undermine the public's trust in the FDA by blocking public access to the practices and procedures that the FDA uses to make policies and decisions.

In addition, employees and former employees involved in employment-related disputes should be able to ask for and receive the personnel policies and practices that directly or indirectly bear on the matters in dispute.

Moreover, the proposed final sentence, "Under this exemption, the agency may also withhold internal records whose release would help some persons circumvent the law," is ***unconstitutionally vague*** because ALL information, be it FDA information or the information in the local newspaper (e.g., death notice information) WOULD help SOME persons (e.g., those we label criminals) to circumvent some aspect of the LAW.

For all of the preceding reasons, the proposed language should be modified as suggested.

Further, the proposed **21 CFR § 20.65** that states:

"Sec. 20.65 National defense and foreign policy.

(a) Records or information may be withheld from public disclosure if they are:
  (1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and
  (2) In fact properly classified under such Executive order.
(b) [Reserved]"

should be changed to read,

"Sec. 20.65 National defense and foreign policy.

(a) Records or information may be withheld from public disclosure if they are:
  (1) Specifically authorized under **publicly disclosed** criteria **that specifically address the activities of the Department of Health and Human Services, in specific, and the FDA, in general** established by ~~an~~ **a constitutionally valid** Executive order to be kept secret in the interest of national defense ~~or foreign policy~~ **provided said withholding does not directly conflict with any statute or judicial mandate**; and
  (2) In fact**,** properly classified under such Executive order.
(b) [Reserved]"

Because the FDA is mandated to protect the health of the American public, the scope of the withholding of a FOIA request under any Executive should be limited to items that are truly in the direct interest of national

defense, but not to foreign policy, since the protection of the health of the American public should trump any foreign policy concern.

Moreover, the withholding must not directly conflict with any statute or judicial mandate because, under the U. S. Constitution, no branch of the government, executive, legislative, or judicial may usurp or ignore the prerogatives the other branches unless the other branches explicitly grant the usurping branch the explicit limited right to so do (e.g., the limited legislative powers given to agencies of the executive branch to draft and promulgate administrative regulations such as those being proposed here by the FDA.

For these reasons, at a minimum, the proposed language should be modified as indicated.

Overall, the proposed regulations, if they are enacted as written, will further erode the public's already weakened trust in the FDA.

Even with the revisions proposed, the revised regulations will still increase the public's skepticism about the FDA's willingness to protect the public health rather than, *as recent events seem to indicate*, knowingly sacrifice the public's health in order to serve the greed-driven interests of the industries (Food, Drug, Cosmetic, Medical Device, Contract Laboratory, Mammography Screening Center, Blood Bank) that the Agency is supposed to be regulating and, *at defined intervals*, periodically inspecting (minimally, bi-annually inspecting Drug, Medical Device, Contract Laboratory firms and, for example, annually inspecting Mammography Screening Centers.]

Finally, should this regulation be "withdrawn because of significant adverse comments," this commenter also offers these observations in whole as a "significant adverse comments" to the companion proposal published at the same time as this proposed rule.