DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0464]

Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to solicit general views and information from interested persons on issues concerning the electronic submission of product information to the agency. In particular, FDA is seeking these views and information from interested persons on the feasibility and effect of an all-electronic submission environment, as well as issues related to an electronic regulatory information exchange platform. To help solicit such information and views, FDA is seeking responses to specific questions (see section IV of this document).

DATES: *Public Hearing*: The public hearing will be held on December 18, 2006, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early.

Registration and Participation: Registration on the day of the public hearing will be provided on a space available basis beginning at 7:30 a.m. Because seating is limited, we recommend arriving early. See section I of the **SUPPLEMENTARY INFORMATION** section of this document for information on how to participate in the meeting. If you need special accommodations due to a

disability, please contact Paula S. McKeever (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Comments: Submit written or electronic notices of participation and comments by December 8, 2006. The administrative record of the hearing will remain open to receive additional comments until February 16, 2007.

ADDRESSES: The public hearing will be held at the Advisors and Consultants Staff Conference Room, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857. Additional information on parking and public transportation may be accessed at *http://www.fda.gov/oc/initiatives/criticalpath/*.

Submit written notices of participation and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic notices of participation and comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdockets.cfm*. Identify all submissions to the docket with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–45, Rockville, MD 20857, 301–827–1520, *paula.mckeever@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meeting

The procedures governing the hearing are set forth in part 15 (21 CFR part 15) of FDA's regulations. If you wish to make an oral presentation during the hearing, you must submit a written notice of participation with the Division of Dockets Management (see **ADDRESSES**) by December 8, 2006. In the written notice, submit your name, title, business affiliation, address, telephone

number, fax number, and e-mail address. You should also submit a written statement for each discussion topic in section IV of this document that you intend to address, or other pertinent information related to the topic in your presentation, the names and addresses of all individuals that plan to participate, and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Participants should submit to the docket two copies of each presentation.

We will file the hearing schedule indicating the order of presentation and the time allotted to each person with the Division of Dockets Management (see **ADDRESSES**). We will also mail or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called, risk forfeiting their scheduled time.

II. Background

Over the past decade, we have been moving toward transforming all regulatory submissions from paper to electronic means. To meet this goal, we have taken the following steps:

- Issued regulations related to voluntary electronic submission of regulatory information and provided a docket listing all submissions that we accept electronically (e.g., electronic records and electronic signatures, 21 CFR part 11; docket 92S–0251; *http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm*);

- Issued regulations requiring or proposing to require electronic submission of certain regulatory information (e.g., the electronic submission of the content of labeling (December 11, 2003; 68 FR 69009), and manufacturer registration and listing of drug products (August 29, 2006; 71 FR 51275));

- Issued numerous guidance documents to assist in the submission of various regulatory documents in electronic format (e.g., electronic common technical document, certain premarket applications, and postmarketing information; see *http://www.fda.gov/cder/guidance/index.htm#electronic%20submissions*);

- Issued notices related to electronic submission (e.g., availability of the FDA electronic submissions gateway (*http://www.fda.gov/esg/default.htm*)); and

- Collaborated with manufacturers, health care information suppliers, and other government agencies to develop data standards, and to build databases for sharing certain clinical trial information.

Now that we have accomplished these preliminary steps, we are considering technological and other feasibility issues related to the electronic submission of premarket applications to FDA , as well as the electronic submission of other regulatory information (e.g., postmarketing information and amendments to applications).

Facilitating electronic submissions and the electronic availability of product information would promote patient safety and better health outcomes, speed development of new medical technology, and allow health care professionals and consumers to make well informed decisions regarding the use of medical products. Such facilitations of electronic submissions would

also support the Secretary's health IT priorities to harness information technology to improve healthcare and patient safety.

As we work towards establishing a modern, paperless submission environment, we have also become aware of the potential benefits of a common electronic platform that could be administered by a third party entity or entities (e.g. private or nonprofit entities not otherwise engaged in clinical research activities) with relevant expertise and organizational leadership to facilitate, coordinate and manage the functions necessary for electronic submissions. For example, a third party entity might perform the following tasks:

- Build an electronic platform,
- Maintain data warehouses,
- Transition existing electronic data and information repositories to the electronic platform,
- Produce other necessary components to facilitate electronic access and management of information,
- Manage and support these functions.

III. Purpose and Scope of the Hearing

The purpose of this public hearing is to provide stakeholders the opportunity to address specific topics (see section IV of this document) and present their views, recommendations, and any other pertinent information related to the scope of this public hearing.

The scope of this public hearing includes the following three issues:

- Feasibility issues related to the electronic submission of premarket applications, including the effects on stakeholders of such actions;

- Feasibility issues related to electronic submissions of other regulatory information, e.g., postmarketing information and amendments to applications; and
- Issues related to the concept and feasibility of an electronic platform that would facilitate the exchange of clinical research information and other regulatory product information, the role of a public private partnership in the creation and assessment of such a platform, and the management of the platform after its creation by a private entity or entities with the relevant technological expertise.

IV. Issues for Discussion

A. Electronic Submissions

We are specifically interested in hearing comments regarding the following questions and any other pertinent information related to the feasibility of the electronic submission of premarket applications and other regulatory information:

1. Transition From Paper Submissions to Electronic Submissions

- Since January 1999, we have accepted the voluntary electronic submission of certain premarket applications. If you are not voluntarily submitting such applications electronically, what is the reason(s)?
- Are you electronically submitting any portion of your premarket application? Is the portion specific to product type or premarket application?
- What are the major impediments to an all-electronic submission environment?
- How can FDA best address these impediments?
- Are there certain types of premarket applications or portions of applications that would be more difficult to submit electronically? Why?

- Are there specific issues related to electronic submission of premarket applications that are unique to small companies, academic institutions, and government agencies? If so, what are they and why are they unique?

- In addition to the sponsors of premarket applications, are there other sectors of FDA regulated industry that would have to make adjustments in business practices in an all-electronic submission environment? Please describe any such adjustments.

- In your opinion, what internal expertise is needed for firms to make the transition to an all-electronic premarket submission? Do firms have this expertise?

- Is the labor market ready to accommodate industry's demand for such expertise to convert applications in an all-electronic submission environment?

- Are there enough entities available to provide such services or tools in support of this effort? If not, how long would it take for these services to become available?

- How would an all-electronic submission environment benefit you?

- Would an all-electronic submission environment change your ability to initiate in a timely manner the studies supporting your regulatory submission?

2. Cost

- What do you estimate as the cost burden to you if all premarket applications and related documents are submitted electronically? What is the breakdown of the cost (e.g., software, programming, hardware, training)?

- Would these costs differ depending on the type of entity providing services related to the application (e.g., sponsor, clinical research organization, U.S. agent)?

- What additional costs are associated with implementing a particular format or standard for an electronic premarket submission?
- Once the appropriate systems and processes are in place, and excluding startup costs, what would be the costs associated with providing an all-paper submission compared to an all-electronic submission?
- Are there parts of a product application that are more costly to convert to an electronic format than others?

3. Time

- Based on your current method of preparation to submit applications, how much time would be required for preparation to submit the entire application in an electronic format; or a portion by an entity providing services related to the application?
- How long would it take you to prepare and submit an application electronically under the current format accepted by FDA for voluntary submissions?
- How much time would you need to make a smooth transition to a new electronic system?
- How would your estimated time differ for various product types or applications?

4. Implementation

- Should we consider an incremental phase-in implementation strategy for an all-electronic submission environment? Is so, what should the strategy include? What is the order of priorities for phasing in implementation?
- What steps can we take to minimize the cost or other burdens of transitioning to an all-electronic submission environment?

- What additional standards or revisions to current electronic standards would be helpful to make electronic submissions work?
- Are the tools and formats currently available for FDA electronic submissions adequate? If not, why? What is needed?
- Are there other submission mechanisms more suitable and beneficial than what is currently available (e.g., the electronic submission gateway)?
- Are there factors, such as data formats or tools, for harmonization with other government entities, the private sector, or foreign regulatory authorities that could reduce costs or increase the benefits of electronic submissions?
- Would issuing guidance be useful in helping with the transition? If so, what topics would you like addressed?

B. Third Party Entities

As previously described in section II of this document, we are considering issues related to the concept and feasibility of an electronic platform that would facilitate the exchange of clinical research information and other regulatory product information, and the role of a public private partnership in the creation and assessment of such a platform. In addition, we are considering whether the functions of the platform could be assumed by a private entity or entities with the relevant technological expertise. Therefore, we are interested in hearing your presentation on the following questions.

- What are your general viewpoints on a third party entity or entities providing services related to such an electronic platform?
- What are your views on the establishment of a public-private partnership to initiate formation of an electronic platform?
- How do you envision the business process modeling and nature of the third party entity or entities?

- What are the necessary attributes and characteristics of the third party entity or entities?
- What services could the third party entity or entities provide?
- What collaborative efforts by FDA with a third party entity would be beneficial to establish services?

V. Notice of Hearing Under 21 CFR Part 15

The Acting Commissioner of Food and Drugs (the Acting Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Office of Policy and Planning, the Office of the Chief Counsel; and by senior management from the National Institutes of Health, particularly the National Cancer Institute.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number found in brackets in the heading of this document, along with the statement ''Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management.'' Requests to make a presentation should contain the potential presenter's name and title; address; telephone and fax number; e-mail address; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; and a brief summary of the presentation (including the discussion topic(s) that will be addressed).

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant.

Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open until February 16, 2007. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions identified by topic to which they refer (see section IV of this document). Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number at the heading of this document. Received comments may be seen in Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

The hearing will be transcribed as stipulated in § 15.30(b). Transcripts of the hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 21 days after the hearing. You may place orders for copies of the transcript through the Freedom of Information Office (HFI–35), Food and

Drug Administration, 5600 Fishers lane, rm. 6–30, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: November 15, 2006.

Janet Woodcock,

Deputy Commissioner for Operations.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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