SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Stakeholder Meeting to Discuss the Possible Implementation of Two Review Performance Goals referenced in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). In a letter that accompanied the user fee legislation, the agency committed to a number of review performance goals. These goals include a commitment that 50 percent of the premarket approval applications received in fiscal year (FY) 2007 will have an FDA decision in 180 days and 80 percent of the premarket notifications will have an FDA decision in 90 days. The letter states that these goals are to be re-evaluated following the end of FY 2005 and FDA is to hold a public meeting to consult with its stakeholders and to determine whether the goals are appropriate for implementation in FY 2007.

DATES: The public meeting will be held on May 22, 2006, from 9 a.m. to 12 p.m. However, depending upon the level of public participation, the meeting may end early. Registration is required by May 19, 2006. All individuals wishing to make a presentation on the implementation of these two performance goals in FY 2007 should indicate their intent and provide an abstract of their presentation by May 10, 2006.

ADDRESSES: The public meeting will be held at the Center for Devices and Radiological Health, 9200 Corporate Blvd., rm. 20B, Rockville, MD 20850.

Submit written requests to make an oral presentation to Cindy Garris (see **FOR FURTHER INFORMATION CONTACT**). Include your name, title, firm name, address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all requests for suggestions and recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 121, FAX: 301–443–8818, e-mail: *cynthia.garris@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act (the act) to authorize user fees for the review of certain premarket applications. In addition, in a letter that accompanied the user fee legislation (goals letter found at: *http://www.fda.gov/cdrh/mdufma/pgoals.html*), the agency committed to a number of review performance goals for premarket applications, including premarket approval applications (PMAs) and premarket notifications (510(k)s) that become more challenging with each FY.

Under the goals letter, 50 percent of the PMAs received in FY 2007 are to have an FDA decision in 180 days and 80 percent of the 510(k)s are to have an FDA decision in 90 days. The goals letter further states that these goals are to be re-evaluated following the end of FY 2005, and FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in FY 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary of Health and Human Services will send a letter to the Committee on Health, Education, Labor, and Pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives, stating that the goal will not be implemented and the rationale for its removal.

Since its passage in October 2002, the agency has been working to implement MDUFMA. An important part of this process has been the annual stakeholder meetings, during which interested persons have been afforded the opportunity to share information and views on the implementation of MDUFMA. FDA is continuing this outreach to its stakeholders by holding this public meeting. During this meeting, FDA encourages stakeholders to provide their input and recommendations on the implementation of these two performance goals in FY 2007.

For additional information on MDUFMA, please see the document entitled ''Background on MDUFMA'' at *http://www.fda.gov/cdrh/mdufma/whitepaper.html*.

II. Agenda

On May 22, 2006, FDA is providing the opportunity for interested persons to share their views on the implementation of the FY 2007 PMA and 510(k) performance goals discussed previously in this document. FDA stakeholders may offer their input and recommendations on these two performance goals.

III. Registration

Online registration for the meeting is required by May 19, 2006. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at *http://www.fda.gov/cdrh/meetings/052206.html*. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/052206.html* by May 19, 2006. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–6597, ext. 121 by May 19, 2006.

If you need special accommodations due to a disability, please contact Cindy Garris at least 7 days in advance of the meeting.

IV. Request for Input and Materials

FDA is also interested in receiving input from stakeholders on other issues related to future user fee legislation. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives on the docket for this document (2005N–0364). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5494 Filed 4–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0022]

International Conference on Harmonisation; Guidance on S8 Immunotoxicity Studies for Human Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''S8 Immunotoxicity Studies for Human

Pharmaceuticals.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides recommendations on nonclinical testing approaches to identify compounds that have the potential to be immunotoxic and guidance on a weight-of-evidence decisionmaking approach for immunotoxicity testing. The guidance is intended to provide recommendations on nonclinical testing for immunotoxicity induced by human pharmaceuticals. The guidance applies to unintended immunosuppression and immunoenhancement, excluding allergenicity or drug-specific autoimmunity.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20857. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6480, Silver Spring, MD 20993–0002, 301–796–0169.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH steering committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 8, 2005 (70 FR 6697), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' The notice gave interested persons an opportunity to submit comments by April 11, 2005. After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH steering committee and endorsed by the three participating regulatory agencies in August 2005.

The guidance provides the following information: (1) Recommendations on nonclinical testing approaches to identify compounds which have the potential to be immunotoxic, and (2) guidance on a weight-of-evidence decisionmaking approach for immunotoxicity testing. The guidance is intended to provide recommendations on nonclinical testing for immunotoxicity induced by human pharmaceuticals. The guidance applies to immunosuppression and immunoenhancement, excluding allergenicity or drug-specific autoimmunity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice