However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 1, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 1, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–6061 Filed 3–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The 10th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following conference: 10th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the Drug, Device, and Biologics industries with an opportunity to interact with FDA reviewers and compliance officers from the Centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answers, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 11 and 12, 2007, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949–608–4413, FAX: 949–608–4417, or OCRA, Attention to Detail (ATD), 5319 University Dr., suite 641, Irvine, CA 92612, 949–387–9046, FAX: 949–387–9047, Web site: *www.ocra-dg.org*.

Registration and Meeting Information: See OCRA Web site, *www.ocra-dg.org*. Contact ATD at 949–387–9046.

Before May 11, 2007, registrations fees are as follows: $575.00 for members, $625.00 for non-members and $400.00 for FDA/Govt/Students. After May 11, 2007, $625.00 for members, $725.00 for non-members, and $400.00 for FDA/Govt/Students.

OCRA student rate applies to those individuals enrolled in a Regulatory or Quality related academic program at an accredited institution. Proof of enrollment required.

The registration fee will cover actual expenses including refreshments, lunch, materials, parking and speaker expenses. If you need special accommodations due to a disability, please contact Linda Hartley at least 10 days in advance.

Dated: March 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6052 Filed 3–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0114]

Electronic Distribution of Prescribing Information for Prescription Drug Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to solicit views and information from interested parties concerning the concept of electronic distribution of FDA-approved prescribing information currently contained in the package insert (or PIs) for human prescription drug and biological products. In particular, FDA is seeking views and information on the feasibility of establishing a modern and efficient process for industry to electronically distribute prescribing information to dispensers. We are seeking input on a number of questions regarding the current use of package inserts and those logistical issues associated with electronic distribution of such prescribing information.

DATES: *Public Hearing*: The public hearing will be held on April 27, 2007, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the public hearing may be extended later or may end early. If you need special accommodations due to a disability, please contact Erik Mettler (see **FOR FURTHER INFORMATION CONTACT**) by April 20, 2007.

Registration: Seating at the public hearing is limited. Registration is free and will be on a first-come, first-serve basis. Persons interested in attending the public hearing should register by close of business on April 20, 2007.

Notice of Oral Presentation: Persons interested in presenting responses to the questions should submit a notice of oral presentation by close of business on April 17, 2007. See section I of this document for information on how to participate in the public hearing.

Comments: Submit written or electronic comments by June 22, 2007.

ADDRESSES: *Public Hearing*: The public hearing will be held at 5600 Fishers Lane, third Fl., conference rooms D & E, Rockville, MD 20857.

Registration: Submit written registration to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic registration to *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*.

Notice of Oral Presentation and Comments: Submit written notices of oral presentation and comments to the Division of Dockets Management (see previous paragraph). Submit electronic notices of oral presentation and comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm*. Identify all submissions to the docket with the docket number found in

brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, *Erik.Mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Public Hearing

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 oral presentation with the Division of Dockets Management (see **ADDRESSES**) by April 13, 2007. 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 a copy 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

The PIs with prescribing information accompany prescription drugs to meet the requirement that ''labeling on or within the package from which the drug is to be dispensed bears adequate information for its use * * * .'' (21 CFR 201.100(c)(1). FDA approves the prescribing information as part of the drug's labeling in the drug application. Currently, the PI containing the prescribing information for the safe and effective use of the product is a paper leaflet. PIs are used in numerous ways by various healthcare entities, including pharmacies that receive and dispense the drug, and provide important drug information for the safe and effective use of the product. Such information includes, among other things, indications, adverse events, warnings and precautions, and dosing instructions. Although the information in the PI is a valuable resource, it is often not readily accessible when a healthcare provider who has not physically received the drug makes a treatment decision or discusses treatments with a patient. Additionally, the PI may not contain the most current information, because the PI accompanying the drug's distribution may have been printed and distributed prior to more recent labeling changes. As the healthcare system advances into the 21st century, we are considering how dissemination of the prescribing information contained in the PI can take advantage of technological advances in the electronic transmission of information.

III. Purpose and Scope of the Hearing

The purpose of the public hearing is to gain a better understanding of how the prescribing information in a PI is currently used by healthcare entities and what the information needs are as we consider new approaches to disseminating labeling information. We are also interested in getting a better understanding of the logistical processes that are currently in place or that might need to be established in order to electronically disseminate the prescribing information, including the costs of these efforts.

In particular, we would like to hear from manufacturers of drug and biological products, pharmacists and pharmacies, other healthcare providers, wholesalers, consumers, and information providers.

IV. Issues for Discussion

To help achieve the objectives discussed in section III of this document, we are specifically interested in hearing comments on the following questions and any other pertinent information related to the electronic distribution of the prescribing information.

A. General

(1) Currently, who uses, and benefits from the prescribing information?

(2) How can electronic distribution and access of the prescribing information be accomplished?

(3) Would electronic distribution and access of the prescribing information improve the public health?

(4) Would electronic distribution and access of prescribing information improve prescribing habits? If so, how?

(5) How might we ensure that changes in the distribution and access of the prescribing information will not negatively affect the current users?

(6) Would an increase in electronic access to prescribing information affect prescribers, pharmacists, and patients? If so, how?

B. Logistics

(1) Generally and without focusing on vendor-specific methods, how can electronic distribution of prescribing information be accomplished?

(2) What are the costs associated with the successful implementation of electronic distribution and access to prescribing information, including start-up and maintenance expenses? Please breakdown costs per healthcare sector.

(3) Is the technology and infrastructure currently available to accomplish electronic distribution and access? If so, what is available? If not, what is needed?

(4) What are other potential barriers to accomplishing the electronic prescribing information?

(5) How can we ensure that electronic prescribing information is accessible to those who need the information?

(6) How do we meet the needs of those who do not have electronic capability?

(7) In case of emergency or when a computer system is down, what might be the backup?

(8) How should electronically disseminated prescribing information be regularly updated and remain current?

(9) What are the roles for the involved parties (manufacturers, third-parties, health professionals, FDA, and consumers)?

(10) Should all products have electronic prescribing information or are there some products or classes of products that should continue to have a paper prescribing information accompany the product?

(11) If electronic prescribing information were to be used instead of paper inserts, then how should electronic prescribing information be implemented? Should electronic prescribing information be phased in? If so, over what time period? Which products should use electronic prescribing information first?

V. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 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, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of oral presentation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). To ensure timely handling of written submissions, 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 Distribution of Package Inserts for Prescription Drug Products.'' Requests to make an oral 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 (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. Requests for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of oral presentation 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 June 22, 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: March 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–1604 Filed 3–28–07; 1:02 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Health Information National Trends Survey 2007 (HINTS 2007)

Summary: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) request a review and approval of the information listed below. The proposed information collection was previously published in the **Federal Register** on October 26, 2006 on page 62597 and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or implemented on or after October 1, 1995 unless it displays a currently valid OMB control number.

Proposed Collection: Title: Health Information National Trends Survey 2007 (HINTS 2007). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Building on the first two rounds of HINTS data collection (*HINTS 2003:* OMB #0925–0507, *Exp. Date:* 8/31/03; and *HINTS 2005:* OMB # 0925–0538, Exp. Date 11/30/2007), HINTS 2007 will continue to provide NCI with a comprehensive assessment of the American public's current access to, and use of, information about cancer, including cancer prevention, early detection, diagnosis, treatment, and prognosis. The content of the survey will focus on understanding the degree to which members of the general population understand vital cancer prevention messages. More importantly, this NCI survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained. HINTS is intended to be the foundation of NCI's effort to build on the opportunities presented by a national shift in communication context (for example, the increase in information available on the Internet and the use of email as a method of communication), and by so doing, improve the nation's ability to reduce the national cancer burden. Data will be used (1) to understand individuals sources of and access to cancer-related information; (2) to measure progress in improving cancer knowledge and communication to the general public; (3) to develop appropriate messages for the public about cancer prevention, detection, diagnosis, treatment, and survivorship; and (4) to identify research gaps and guide decisions about NCI's research efforts in health promotion and health communication. *Frequency of Response:* One time. *Affected Public:* Individuals. *Type of Respondents:* U.S. Adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 11,670; *Estimated Number of Responses per Respondent:* 1.36; *Average Burden Hours per Response:* .24; and *Estimated Total Annual Burden Hours Requested:* 3,739. The annualized cost to respondents is estimated at: $59,824. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.