IND effective date was July 17, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: August 16, 1999. The applicant claims August 24, 1999, as the date the new drug application (NDA) for VISUDYNE (NDA 21–119) was initially submitted. However, FDA records indicate that NDA 21–119 was submitted on August 16, 1999.

3. *The date the application was approved*: April 12, 2000. FDA has verified the applicant's claim that NDA 21–119 was approved on April 12, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. 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 November 29, 2004. 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 March 28, 2005. 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: August 30, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–21678 Filed 9–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0423]

Second Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002 Provisions; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Second Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The topic of discussion is the agency's progress in implementing the various MDUFMA provisions, including the guidances FDA has issued on the new law.

DATES: The public meeting will be held on November 18, 2004, from 9 a.m. to 5 p.m. Registration is required by Friday, October 22, 2004. All individuals wishing to make a presentation or to speak on an issue should indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by October 22, 2004. Time for presentations will be limited to 10 minutes.

ADDRESSES: The public meeting will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Submit written requests to make an oral presentation to 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: *cxg@cdrh.fda.gov*. 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 request 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: *cxg@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act to include several new significant provisions. MDUFMA authorizes the following provisions: (1) User fees for certain premarket applications, (2) establishment of good manufacturing practice (GMP) inspections by FDA-accredited persons (third-parties), and (3) new requirements for reprocessed single-use devices. In addition, the new law contains several provisions that, while narrower in scope than the previously mentioned provisions, are significant changes to the device law. These include a modular review program for premarket approval applications (PMAs), electronic labeling for certain prescription devices, several provisions concerning devices for pediatric use, and a new labeling requirement that requires the manufacturer's name to appear on the device itself, with certain exceptions.

The agency has been working to implement the new law since its passage in October 2002. During this time, FDA has accomplished the following significant milestones: (1) Established a user fee program with payment, billing, and appeals procedures; (2) published accreditation criteria for persons conducting third-party inspections and accredited 15 such persons; (3) identified certain reprocessed single-use devices that will be subject to additional marketing requirements; and (4) published guidances related to the PMA, premarket notification (510(k)), and biologics license application (BLA) programs, bundling multiple devices in a single application, and premarket review of pediatric devices. The agency is drafting additional documents to be issued in the near future.

II. Agenda

On November 18, 2004, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. The following topics will be discussed:

- User Fees Process—This panel will consider the small business determination and the user fee payment processes.

Premarket Review Performance Goals—This panel will discuss the agency's progress in meeting the PMA, 510(k), and BLA review performance goals.

- Qualitative Performance Goals (e.g., Modular PMA and GMP and

Bioresearch Monitoring (BIMO) Inspection Programs)— This panel will discuss the agency's progress in developing various qualitative performance goals, such as those related to the modular PMA and GMP inspection programs. This panel will also discuss internally-established milestones for the BIMO inspection process.

• Third-Party Inspection Program— This panel will discuss implementing guidances for the program, including establishment eligibility criteria for inspection by a third party.

• Reuse— This panel will discuss the FDA-identified reprocessed single-use devices that require submission of certain validation data and the guidance that describes the agency's review procedures for such submissions. This panel will also report on FDA's progress in reviewing the validation data submissions.

At the conclusion of the meeting, there will be a general discussion from the floor.

III. Registration

Online registration for the meeting is required by October 22, 2004. 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/120303.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/120303.html* by October 22, 2004. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–6597, ext. 121 by October 22, 2004.

If you need special accommodations due to a disability, please contact Cindy Garris at 301–443–6597, ext. 121 at least 7 days in advance.

IV. Request for Suggestions, Recommendations, and Materials

FDA is particularly interested in receiving suggestions from stakeholders on other topics for discussion. The agency is interested in receiving recommendations about other provisions yet to be implemented both in terms of their priority for implementation and specifics on the implementation itself. 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 (2004N–0423). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

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

Dated: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21676 Filed 9–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0422]

Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (#173) entitled ''Guidance For Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA).'' This draft guidance describes how FDA intends to implement the Federal Food, Drug, and Cosmetic Act (the act) as it relates to animal drug sponsor fees.

DATES: Submit written or electronic comments on the draft guidance by October 28, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act of 2003 (ADUFA), enacted on November 18, 2003, amends the act by adding sections 739 and 740 (21 U.S.C. 379j-11 and 379j-12). Section 740 requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. This draft guidance represents FDA's current thinking on how it intends to implement the animal drug sponsor fee provision of ADUFA.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This draft guidance is being issued as a level 1 guidance consistent with our good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of the applicable statutes and regulations.

III. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance 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.

IV. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [2004D–0422]