TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (Includes Screening)	Total Hours
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication)	10	200	9	1.58	2,844
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, online sales of medical products, latex gloves)	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, and consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468
Total		28	286	9	1.78	4,252

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Annually, FDA projects about 28 focus group studies using 186 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: March 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5505 Filed 3–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0252]

Determination of Regulatory Review Period for Purposes of Patent Extension; A180

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for A180 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit written comments and petitions 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*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA approved for marketing the animal drug product A180 (danofloxacin mesylate). A180 is indicated for treatment of bovine respiratory disease associated with *Mannheimia* (*Pasteurella*) *haemolytica* and *Pasteurella multocida* in beef cattle. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for A180 (U.S. Patent No. 4,861,779) from Pfizer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of A180 represented the first permitted commercial marketing or use

of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for A180 is 5,365 days. Of this time, 5,314 days occurred during the testing phase of the regulatory review period, while 51 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective*: January 14, 1988. The applicant claims January 20, 1988, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was January 14, 1988, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: August 1, 2002. FDA has verified the applicant's claim that the new animal drug Application (NADA) for A180 (NADA 141–207) was initially submitted on August 1, 2002.

3. *The date the application was approved*: September 20, 2002. The applicant claims September 24, 2002, as the date NADA 141–207 was approved. However, FDA records indicate that the date of approval was September 20, 2002.

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 1,826 days 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 May 29, 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 September 24, 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 are to 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. E7–5504 Filed 3–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0090]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 13, 2007, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select ''2007N–0090'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on May 30, 2007. All comments will be posted without change, including any personal information provided. Comments received on or before May 30, 2007, will be provided to the committee before or at the meeting.

Location: Hilton Silver Spring, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Cathy A. Groupe, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Cathy.Groupe@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) 21–888, proposed tradename Zimulti (rimonabant), 20 milligrams tablets, Sanofi-Aventis, as an adjunct to diet and exercise for obesity management in patients with a body mass index equal to or greater than 30 kilograms (kg) per square meter, or a body mass index equal to or greater than 27 kg per square meter if accompanied by at least one cardiovascular risk factor.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 30, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 22, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak on or before May 21, 2007.