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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Recall Status Reports and Follow-up 7.53	2,166	4	8,664	10	86,640
Termination of a Recall 7.55(b)	2,166	1	2,166	10	21,660
Total					216,600

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

The annual reporting burdens are explained as follows:

I. Reporting

A. Recall Strategy

Request firms develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the agency estimates it will receive 2,166 responses annually.

B. Firm Initiated Recall and Recall Communications

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, and biologicals to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the agency estimates it will receive 2,166 responses annually for each.

C. Recall Status Reports

Request that recalling firms provide periodic status reports so the FDA can ascertain the progress of the recall. This collection of information will generate approximately 8,664 responses annually.

D. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The agency estimates it will receive 2,166 responses annually.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12339 Filed 6–2–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0335] (formerly Docket No. 2007E–0133) and [Docket No. FDA–2007–E–0227] (formerly Docket No. 2007E–0148)

Determination of Regulatory Review Period for Purposes of Patent Extension; TYZEKA; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 15, 2008 (73 FR 28119), announcing FDA's determination of the regulatory review period for TYZEKA. The document published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning and Preparedness (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7630.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–10857, published on May 15, 2008 (73 FR 28119), the following correction is made:

On page 28119, in the third column, in the Docket No. heading, ''Docket No. FDA–2007–E–0035'' is corrected to read ''Docket No. FDA–2007–E–0335''.

Dated: May 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12300 Filed 6–2–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0458 (formerly Docket No. 2007E–0144) and Docket No. FDA–2007–E–0460 (formerly Docket No. 2007E–0176)]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VEREGEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human drug product VEREGEN (kunecatechins). VEREGEN is indicated for the topical treatment of external genital and perianal warts in immunocompetent patients 18 years and older. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for VEREGEN (U.S. Patent Nos. 5,795,911 and 5,968,973) from Mitsui Norin Co., Ltd., and Cancer Institute (Hospital), Chinese Academy of Medical Sciences, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated July 24, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VEREGEN 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 VEREGEN is 3,002 days. Of this time, 2,605 days occurred during the testing phase of the regulatory review period, while 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 14, 1998. The applicant claims August 13, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 1998, 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*: September 30, 2005. The applicant claims September 23, 2005, as the date the new drug application (NDA) for VEREGEN (NDA 21–902) was initially submitted. However, FDA records indicate that NDA 21–902 was submitted on September 30, 2005.

3. *The date the application was approved*: October 31, 2006. FDA has verified the applicant's claim that NDA 21–902 was approved on October 31, 2006.

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 1,300 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 August 4, 2008. 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 December 1, 2008. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

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

[FR Doc. E8–12296 Filed 6–2–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labeling Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas (UA), is announcing a public workshop entitled ''Food Labeling Workshop.'' This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on August 12, 2008, from 8 a.m. to 5 p.m., and on August 13, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Continuing Education Center, 2 East Center St., Fayetteville, AR (located downtown).

Contact: David Arvelo, Small Business Representative, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, or email: *david.arvelo@fda.hhs.gov*.

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or email: *seideman@uark.edu*.

Registration: You are encouraged to register by July 29, 2008. The University of Arkansas requires a $150 registration fee to cover the cost of facilities, materials, and breaks. Seats are limited;