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