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

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Completed survey	44,500	1	44,500	.75	33,375
Total domestic	61,500		61,500		34,514
Foreign Facilities					
Screening questions only	14,000	1	14,000	.067	938
Completed survey	26,000	1	26,000	.75	19,500
Total foreign	40,000	1	40,000		20,438
Grand total	101,500				54,952

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

These estimates of the number of respondents and the burden hours per response are based on FDA's registration database and FDA and the contractor's experience with previous surveys. The respondents are divided into two groups: Domestic and foreign. We estimate the number of domestic facilities at 126,000 based on information in the registration database. However, we do not expect that all of these firms will participate in the survey. We anticipate that approximately 61,500 facilities will participate, which takes into account typical response rates to these types of surveys and inaccurate contact information that facilities have entered into the registration database (see *http://www.cfsan.fda.gov/~furls/ffregacc.html*). Similarly, among the 81,000 foreign facilities in the registration database, we expect that 40,000 foreign facilities will respond.

We estimate that it will take a respondent 4 minutes (.067 hours) to complete the screening questions and 45 minutes (0.75 hours) to complete the entire survey. Prior to the administration of the survey, the agency plans to conduct a pretest of the final survey to identify and resolve potential problems. The pretest will be conducted with nine participants.

Dated: May 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8783 Filed 5–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0363]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 7, 2007, the comment period for a draft guidance entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' FDA published a notice of availability of the draft guidance in the **Federal Register** of October 31, 2006 (71 FR 63774). The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirement of special controls for class II devices, if the device is reclassified. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on a proposed rule to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls)

DATES: Submit written or electronic comments on the draft guidance by June 7, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). In the same issue of the **Federal Register** (71 FR 63774), FDA published a notice of availability of a draft guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirement of special controls if they were reclassified. FDA invited interested persons to comment on the proposed

rule and on the draft guidance document by January 29, 2007.

Two companies requested FDA to extend the comment period on the proposed rule by 90 days because the proposal presented complex medical and scientific issues that required the company to assemble a team of many different specialties in order to prepare their comments. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on the proposed rule for 30 days. Because the issues presented by the guidance document are intertwined with those presented by the proposed rule, FDA is reopening the comment period on the guidance document for the same period.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive the draft guidance document entitled ''Class II Special Controls Document: Absorbable Hemostatic Device,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1558 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including

lists of approved submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

III. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the 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.

Dated: April 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8780 Filed 5–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0027]

Voluntary Self-Inspection of Medicated Feed Manufacturing Facilities; Draft Compliance Policy Guide; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to June 8, 2007, the comment period for the notice of availability that appeared in the **Federal Register** of February 12, 2007 (72 FR 6572). In the notice, FDA requested comments on the draft compliance policy guide on voluntary self-inspection of medicated feed manufacturing facilities. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by June 8, 2007.

ADDRESSES: Submit written comments on the draft compliance policy guide 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT: Paul Bachman, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9225, e-mail: *Paul.Bachman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 12, 2007 (72 FR 6572), FDA published a notice of availability with a 75-day comment period to request comments on a draft compliance policy guide (CPG) on voluntary self inspection of medicated feed manufacturing facilities. The purpose of this CPG is intended to provide guidance to FDA field offices on considering, among other factors, the conduct of self-inspections when prioritizing inspections of medicated feed manufacturing facilities for compliance with Current Good Manufacturing Practices for Medicated Feeds regulations.

The agency has received a request for an extension of the comment period for the draft compliance policy guide. This request conveyed concern that the current 75-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the compliance policy guide.

FDA has considered the request and is reopening the comment period for the draft compliance policy guide until June 8, 2007. The agency believes this reopening allows adequate time for interested persons to submit comments.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on these documents. 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.

Dated: May 1, 2007.

David Horowitz,

Assistant Commissioner for Regulatory Affairs.

[FR Doc. E7–8781 Filed 5–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review—Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.