

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Item	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
MedSun facilities participating in the electronic reporting of adverse events program	400	15	6,000	0.75	4,500
MedSun facilities' electronic responses to Public Health Questions (PHQs)	400	10	4,000	0.5	2,000
Total hours					6,500

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

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-30583 Filed 12-6-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0083]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 18, 2010 (75 FR 34744), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0339. The approval expires on November 30, 2013. A copy of the supporting statement for

this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0056] (formerly 2004N-0234)

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to seek public comment on possible topics for future guidance document development or revisions of existing ones.

DATES: Submit either electronic or written comments on this list and on any agency guidance document at any time.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: For general information regarding FDA's GGP policy contact: Lisa Helmanis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., WO32, rm. 3216, Silver Spring, MD 20993-0002, 301-796-9135.

For information regarding specific topics or guidances, please see contact persons or specific offices listed in the table in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of September 19, 2000 (65 FR 56468), FDA issued its final rule on GGPs (21 CFR 10.115). GGPs are intended to ensure involvement of the public in the development of guidance documents and to enhance understanding of the availability, nature, and legal effect of such guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the Agency committed to publishing an annual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The Agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents (65 FR 56468 at 56477; 21 CFR 10.115(f)(5)).

The Agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the Agency is considering. The Agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

The guidance documents are organized by the issuing Center or Office within FDA, and in some cases are further grouped within the issuing Center or Office by topic categories.

II. Center for Biologics Evaluation and Research (CBER)