DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0328]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on food additive petitions regarding animal feed.

DATES: Submit written or electronic comments on the collection of information by October 31, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information 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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Additive Petitions—21 CFR Part 571 (OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act (21 U.S.C. 348), procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but attempt to explain the requirements and provide a standard format for submission to speed the processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 573 and 582. The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

On September 29, 2004, OMB approved a new information collection on food additive petitions submitted by the Center for Veterinary Medicine (CVM), FDA. The terms of clearance for this information collection stated that, given the interrelatedness of this collection to the information collected under OMB control number 0910–0016 by the Center for Food Safety and Applied Nutrition (CFSAN), FDA should consider merging the two collections. In consultation with CFSAN, CVM has decided not to merge these two collections, because what was once a food additive petitions approval (0910–0016), is now also the approval for affirmation of generally recognized as safe (GRAS) status (formerly OMB control number 0910–0132), labeling requirements for color additives (other than hair dyes) and petitions (formerly OMB control number 0910–0185), electronic submission of food and color additive petitions (formerly OMB control number 0910–0480), and substances approved for use in the preparation of meat and poultry products (formerly OMB control number 0910–0461). Thus, adding one CVM process to a collection now containing four dissimilar CFSAN processes is not justifiable anymore. Finally, the CVM food additive petition process stems from a different section of the CFR and the two processes are handled separately. CVM's food additive petition process relates to part 571; CFSAN's process relates to 21 CFR part 171. There is no efficiency in discussing these separate processes in a single collection of information.

Respondents are expected to be the veterinary feed industry.

FDA estimates the burden of this collection of information as follows:

The estimated annual burden for this information collection is 18,000 hours.

Food additive petitions submitted to CVM are estimated to fall into one of two categories of complexity that also can be used to represent estimates of the information collection burden for food additive petitions. These include only expected petitions for food additives not eligible for exemption under new section 409(h) of the act (21 U.S.C. 348(h)).

Under § 571.1(c) moderate category, for food additive petitions without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of one petitions of this type is received on an annual basis, resulting in a burden of 3,000 hours.

Under § 571.1(c) complex category, for a food additive petition with

complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

Under § 571.6, for a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type are received on an annual basis, resulting in a burden of 5,200 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6	2	2	4	1,300	5,200
Total					18,200

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

Dated: August 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14510 Filed 8–31–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Annual Guidance Agenda

[Docket No. 2004N–0234]

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 written or electronic comments on this list and on any agency guidance documents at any time.

ADDRESSES: Submit written comments 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:

For general information regarding FDA's GGP policy: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

For information regarding specific topics or guidances: Please see contact persons listed in the table in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA's 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 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 by topic categories. The agency's contact persons for each specific area are listed in the tables that follow.

II. Center for Biologics Evaluation and Research (CBER)

TITLE/TOPIC OF GUIDANCE	CONTACT
CATEGORY—COMPLIANCE AND INSPECTION	Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.
Design, Operation, and Validation of Heating, Ventilation, and Air Conditioning (HVAC) Systems Used in the Manufacture of Products Regulated by the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research	Same as above (Do)
CATEGORY—BLOOD AND BLOOD COMPONENTS	
Reentry Algorithm for Donors Who Are Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)	Do