Dated: June 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–15432 Filed 6–19–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0726]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; General Licensing Provisions: Changes to an Approved Application, Labeling, and Revocation and Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 20, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Licensing Provisions: Changes to an Approved Application, Labeling, and Revocation and Suspension (OMB Control Number 0910–0315)—Extension

Under Section 351 of the Public Health Services Act (PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meet standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations.

In part 601 (21 CFR part 601), § 601.2(a) requires a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. Section 601.12(b), (c), and (d) requires applicants to follow specific procedures in informing FDA of each change, established in an approved license application, in the product, production process, quality controls, equipment, facilities, or responsible personnel depending on the potential for the change to have a substantial, moderate, minimal or no adverse effect on the safety or effectiveness of the product. Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval prior to distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures in reporting labeling changes to FDA. Section 601.12(f)(4) requires advertising and promotional labeling and any changes to be reported to FDA. Section 601.45 requires applicants to submit to the agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements. In addition to §§ 601.2 and 601.12, there are other regulations that relate to certain information submitted in a license application or supplement as follows: Part 640 (21 CFR part 640), specifically §§ 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a), and (b)(2); 21 CFR 660.51(a)(4) and 680.1(b)(2)(iii) and (c). The burden associated with the information collection requirements in these regulations is included in the burden estimate for § 601.2, reported under OMB Control No. 0910–0427, and § 601.12 in table 1 of this document. Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requests that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Section 601.5(a) requires a licensee to give notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the licensee to notify selling agents and distributors upon suspension of its license, and provide FDA with records of such notification.

Form FDA 2567 is used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by the Center for Biologics Evaluation and Research (CBER). For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by the Center for Drug Evaluation and Research. In August of 1998, FDA revised and harmonized Form FDA 2253 to enable the form to be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure that the submission is complete.

The number of respondents is based on the estimated annual number of manufacturers that submitted the required information to FDA. There are an estimated 350 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The

total annual responses is based on the estimated number of submissions (i.e., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) received annually by FDA. The rate of submissions are not expected to change significantly in the next few years. The hours per response are based on past FDA experience with the various submissions or notifications. Additional information regarding these estimates is provided below as necessary.

Under § 601.2(a), the total annual responses is based on the numbers of applications submitted to FDA for approval to market a biological product. The estimated burden hours include the time required to fill out the form and collate the documentation. The estimated burden hours to prepare the labeling information submitted with a license application are included in the burden hours to submit a license application that are reported under OMB Control No. 0910–0427.

Under § 601.12(f)(1), (f)(2), and (f)(3), the estimated burden hours include the time to prepare the supplement, fill out the form, and collate the documentation.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. In fiscal year 1999, CBER received 3,784 submissions of advertising and promotional labeling from 114 manufacturers. FDA estimates that approximately 55 percent of those submissions were received with Form FDA 2567 resulting in an estimated 2,081 submissions by 63 manufacturers. The estimated burden hours include the time to prepare the submission, fill out the form, and collate the documentation. The burden hours for the remaining submissions received using Form FDA 2253 are reported under OMB Control No. 0910–0376.

Under §§ 601.12(b) through (d), and 601.12(e), the estimated burden hours include the time to prepare the appropriate supplement or protocol, respectively, and collate the documentation.

Under §§ 600.15(b) (21 CFR 600.15(b)) and 610.53(d), FDA receives very few requests for an exemption or modification to the requirements, therefore, FDA has estimated one respondent per year in table 1 of this document to account for the rare instance in which a request may be made. The estimated burden hours include the time to prepare the request for modification or exemption.

Under § 601.25(b)(3), FDA estimates no burden for this regulation because all requested data and information had been submitted by 1974. Under § 601.26(f), FDA estimates no burden for this regulation because there are no products designated to require further study and none are predicted in the future. However, based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may find further study necessary. As a result, any changes to product labeling would be reported under § 601.12. The information collection requirements for § 601.12 are reported under OMB control number 0910–0315.

Under § 601.5(a), the total annual responses are based on the estimated annual number of notifications received by FDA to discontinue either an establishment and/or product license(s). The estimated burden hours include the time to prepare and submit a letter of discontinuance.

Under § 601.6(a), the number of respondents (21) is based on FDA estimates that establishments would need to notify an average of 20 selling agents and distributors of such suspension, and provide FDA with the records of such notification. The number of respondents is based on the estimated annual number of suspensions by FDA of an establishment or product license(s). The estimated burden hours includes the time to prepare a notification letter and submit record of such notification to FDA.

In the **Federal Register** of March 7, 2000 (65 FR 12011), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Form FDA No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
601.2(a)	2567 and 356h[2]	17	3.71	63	2	126
601.12(f)(1)	2567	12	1	12	40	480
601.12(f)(2)	2567	10	1	10	20	200
601.12(f)(3)	2567	70	1.43	100	10	1,000
601.12(f)(4) and 601.45	2567	63	33.03	2,081	10	20,810
601.12(b)(1) and (b)(3)	356h[2]	190	4.75	903	80	72,240
601.12(c)(1) and (c)(3)	356h[2]	98	2.60	255	50	12,750
601.12(c)(5)	356h[2]	34	1.21	41	50	2,050
601.12(d)	356h[2]	166	1.37	227	10	2,270
601.12(e)	356h[2]	14	1.43	20	20	400
600.15(b)	356h[2]	1	1	1	8	8
610.53(d)	356h[2]	1	1	1	8	8
601.25(b)(3)	NA	0	0	0	0	0
601.26(f)	NA	0	0	0	0	0
601.5(a)	NA	33	1	33	.33	11
601.6(a)	NA	2	10.50	21	.33	7
Total						112,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The burden hours for the use of Form FDA 356h are reported under OMB Control No. 0910–0427.

Dated: June 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–15429 Filed 6–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0505]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Protein Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 20, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Title: Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR Part 589—(OMB Control No. 0910–0339)—Extension

Description: This rule (§ 589.2000 (21 CFR 589.2000)) provides that protein derived from mammalian tissue (with some exceptions) for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348). Proteins derived from animal tissues contained in such feed ingredients in distribution cannot be readily identified (i.e., species), by recipients engaged in the manufacture, processing and distribution, and use of animal feeds and feed ingredients.

Thus, under the agency's authority in section 701(a) of the act (21 U.S.C. 371(a)), to issue regulations for the efficient enforcement of the act, this rule places three general requirements on persons that manufacture, blend, process, distribute, or use products that contain or may contain protein derived from mammalian tissues and feeds made from such products. The first requirement is for cautionary labeling of these products with direct language developed by FDA. This labeling requirement is exempt from the scope of the PRA because it is a ''public disclosure of information originally supplied by the Federal Government for the purpose of disclosure to the public'' (5 CFR 1329.3(c)(2)).

The second requirement is for establishments to maintain and make available to FDA, records that are sufficient to track any material that contains protein derived from mammalian tissues (as defined in § 589.2000(a)(1)), throughout the material's receipt, processing, and distribution. Based on available information, FDA believes that maintenance of these records is a usual and customary part of normal business practices for these firms. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The third requirement is that individuals or firms that manufacture, blend, process, or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. An estimate of the burden resulting from this recordkeeping requirement is provided in table 1 of this document. The estimate is based on the time required to develop written procedures.

Respondents to this collection of information are individuals or firms that manufacture, blend, process distribute, or use feed or feed ingredients that contain or may contain protein that may be derived from mammalian tissue.

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

TABLE1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Response	Total Annual Records	Hours per Record	Total Hours
589.2000(e)(1)(iv)	1,030	1	1,030	14	14,420

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

The estimated number of respondents, persons that separate mammalian and nonmammalian materials, is derived from inspections of firms handling animal protein intended for use in animal feed. The estimate of the time required for this recordkeeping requirement is based on agency records and communication with industry.

Dated: June 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration