records be maintained to document the following: (1) The results and interpretation of all required infectious disease tests, (2) information on the identity and relevant medical records of the donor, (3) the receipt and/or distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from the Center for Biologics Evaluation and Research's (CBER's) database system, FDA estimates that there are approximately 190 tissue establishments of which 105 are conventional tissue banks and 85 are eye tissue banks. Based on information provided by industry, there are an estimated total of 1,500,000 conventional tissue products and 84,789 eye tissue products recovered per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 23,295 donors of conventional tissue and 42,649 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirement in 21 CFR part 1270. Based on information provided by CBER's database system, 76 percent of the conventional tissue banks are members of AATB (105 X 76 percent = 80), and 96 percent of eye tissue banks are members of EBAA (85 X 96 percent = 82). Therefore, recordkeeping by these 162 establishments (80 + 82 = 162) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 28 establishments, which is 15 percent of all establishments (190 - 162 = 28, or 28/190 = 15 percent).

Based on CBER's database system and information provided by industry, FDA estimates an average of two new tissue banks annually, which may be non-members of a trade association. Each new tissue bank requires an estimated 64 hours to prepare standard operating procedures (SOPs) under § 1270.31(a) through (d). The requirement for the development of these written procedures is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures for § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h), include documenting the results and interpretation of all required infectious disease tests and results and the identify and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1270.31(a), (b), (c), and (d)	2	1	2	64	128
1270.31(a), (b), (c), and (d)[2]	28	1	28	24	672
1270.31(a) and 1270.31(b)[3]	28	2	46	1	46
1270.33(a), (f), and (h), and 1270.35(a) and (b)	28	8,843	247,610	1	247,610
1270.35(c)	28	16,980	475,436	1	475,436
1270.35(d)	28	2,123	59,430	1	59,430
Total					783,322

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Review and update of SOPs.
[3]Documentation of deviations from SOPs.

Dated: November 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20477 Filed 12–01–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0494]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by January 3, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (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.

Cosmetic Labeling Regulations—21 CFR Part 701

The Federal Food, Drug, and Cosmetic Act (the act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 502, 601, 602, 603, 701, and 704 of the act (21 U.S.C. 321, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the act or misbranded under section 602 of the act.

FDA's cosmetic labeling regulations are published in part 701 (21 CFR part 701). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

FDA's cosmetic labeling regulations, as published in the **Federal Register** on March 15, 1974 (39 FR 10054 at 10056), and subsequently amended, most recently on March 17, 1999 (64 FR 13254 at 13297), remain unchanged by this notice. FDA is publishing this notice in compliance with the PRA. This notice does not represent any new regulatory initiative.

In the **Federal Register** of January 18, 2006 (71 FR 2947), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
701.3	1,518	21	31,600	1	31,600
701.11	1,518	24	36,340	1	36,340
701.12	1,518	24	36,340	1	36,340
701.13	1,518	24	36,340	1	36,340
Total					140,620

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

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: A declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

According to the 2001 census, there are 1,518 cosmetic product establishments in the United States (U.S. Census Bureau, *http://www.census.gov/epcd/susb/2001/us/US32562.HTM*). FDA calculates label design costs based on stock keeping units (SKUs) because each SKU has a unique product label. Based on data available to the agency and on communications with industry, FDA estimates that cosmetic establishments offered 94,800 SKUs for retail sale in 2005. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that FDA discusses in this information collection, § 701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§ 701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. FDA estimates that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the agency's experience with other products, FDA estimates that cosmetic establishments may redesign up to one-third of SKUs per year. Therefore, FDA estimates that the annual frequency of response will be 21 (31,600 SKUs) for § 701.3 and 24 each (36,340 SKUs) for §§ 701.11, 701.12, and 701.13.

FDA estimates that each of the required label elements may add approximately 1 hour to the label design process. FDA bases this estimate on the hour burdens the agency has previously estimated for food, drug, and medical device labeling and on the agency's knowledge of cosmetic labeling. Therefore, FDA estimates that the total hour burden on members of the public for this information collection is 140,620 hours per year.

Dated: November 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20478 Filed 12–01–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Original Abbreviated New Animal Drug Application; Pyrantel Pamoate Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved an original abbreviated new animal drug