Opportunity Reconciliation Act of 1996, Federal law mandate that all States enact UIFSA by January 1, 1998. The standard interstate forms in this information collection will assist the States in making the transition from URESA to UIFSA.

Respondents: State governments, Guam, Virgin Islands, Puerto Rico and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal No. 1	54	11,947	25 minutes	268,805.4
Transmittal No. 2	54	2,987	5 minutes	13,440.2
Transmittal No. 3	54	597	10 minutes	5,376.1
Uniform Petition	54	5,973.5	7 minutes	37,632.8
General Testimony	54	7,168	20 minutes	129,026.6
Affidavit/Paternity	54	2,987	15 minutes	40,320.8
Locate Data Sheet	54	358	5 minutes	1,612.8
Notice/Cntrl Order	54	8,960	10 minutes	80,641.7
Registration Statement	54	7,885	10 minutes	70,964.6
Estimated Total Annual Burden Hours: 647,821.				

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: February 24, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–4953 Filed 2–27–97; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 97N–0040]

Agency Information Collection Activities: Proposed Collection; Comment Request

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, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of the food safety practices of food processors.

DATES: Submit written comments on the collection of information by April 29, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (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. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (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.

Survey of Food Safety Practices of Food Processing Firms—New Collection

FDA is evaluating the marginal costs of requiring food processors to use Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is already required for seafood processors, and FDA is considering whether to issue regulations requiring HACCP for processors of other foods under the agency's jurisdiction. The analysis of marginal costs requires information about the prevalence of specific HACCP systems and practices among food manufacturers and repackers. FDA will collect this information through an anonymous voluntary survey of a random sample of food processors. Additionally, through a series of on-site visits to selected processors, a contractor will collect information on the marginal cost of various procedures required to operate a HACCP system. The information will help the Center for Food Safety and Applied Nutrition determine the baseline level of HACCP

use from which to estimate the economic costs to the industry of mandatory HACCP regulations for foods other than seafood. FDA will use this information in tailoring any HACCP regulations that may issue so that costs and benefits of such regulations are appropriately considered.

FDA estimates the burden of this survey as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 1—Computer Assisted Telephone Interview (CATI)					
Respond to initial recruitment telephone call	1,231	1	1,231	0.2	246.2
Receive and read introductory letter, key term definitions	1,231	1	1,231	0.25	307.75
Obtain data to prepare for the telephone interview	1,231	1	1,231	0.35	430.85
Respond to telephone interview	1,231	1	1,231	0.5	615.50
Totals		1			1,600.3
Part 2—On-Site Cost Interview					
Receive initial recruitment telephone call	17	1	17	0.2	3.4
Receive and read introductory letter and materials	17	1	17	0.25	4.25
Obtain data to prepare for the site visit	17	1	17	0.5	8.5
Respond to questions during site visit	17	1	17	3.0	51.0
Followup questions	17	1	17	0.25	4.25
Total burden hours, on-site interviews					71.4

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

The total burden hours for Part 1—CATI and Part 2—On-Site Cost Interview are 1,671.7.

The burden hour estimates are based on a pretest conducted with three focus groups.

Dated: February 20, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4955 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0269]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXCENEL® Sterile Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EXCENEL® Sterile Suspension and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product EXCENEL® Sterile Suspension (ceftiofur hydrochloride). EXCENEL® Sterile Suspension is indicated for the treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus (Haemophilus) pleuropneumoniae, Pastureruella multocida, Salmonella choleraesuis,* and *Streptococcus suis* Type 2. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EXCENEL® Sterile Suspension (U.S. Patent No. 4,902,683) from Pharmacia & Upjohn Co. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 21, 1996, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of EXCENEL® Sterile Suspension represented the first