

prior to each public meeting in order to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

CMS policy requires that every foreign visitor is assigned a host. The host/hosting official is required to inform the Division of Critical Infrastructure Protection (DCIP) at least 12 business days in advance of any visit by a foreign national visitor. Foreign National visitors will be required to produce a valid passport at the time of entry.

Attendees that are Foreign Nationals need to identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Visitor's full name (as it appears on passport).

- Gender.
- Country of origin and citizenship.
- Biographical data and related information.
- Date of birth.
- Place of birth.
- Passport number.
- Passport issue date.
- Passport expiration date.
- Dates of visits.
- Company Name.
- Position/Title.

**Authority:** Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh).

Dated: February 10, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011-3812 Filed 2-24-11; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

Proposed Projects:

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Assistance Program Estimates: ORR-1 .....	46	1	2	92
<i>Estimated Total Annual Burden Hours:</i> .....				92

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 22, 2011.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011-4278 Filed 2-24-11; 8:45 am]

**BILLING CODE 4184-01-P**

*Title:* Refugee Assistance Program Estimates: CMA—ORR-1.

*OMB No.:* 0970-0030.

*Description:*

*The Refugee Assistance Program Estimates:* ORR-1 form is the application for funding for the Refugee Cash and Medical Assistance program. Applicants for funding provide estimates of costs of the different components of the program—Refugee Cash Assistance, Refugee Medical Assistance, Health Screening, Services to Unaccompanied Refugee Minors, Administrative Cost of the Services to Unaccompanied Refugee Minors program, and Administrative Costs of the State Refugee Coordinator. Applicants also submit a narrative justification for their estimates. Applicants submit the form annually on August 15 of the fiscal year prior to the fiscal year for which funds are being requested. The form may be submitted through an On-Line Data Collection system or hard copy format. The Office of Refugee Resettlement uses the cost estimate data from the ORR-1 in determining and allocating quarterly awards of funds and in projecting full year costs of this program.

*Respondents:*

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0597]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species**

**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 March 28, 2011.

**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: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0620. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, [Juanmanuel.vilela@fda.hhs.gov](mailto:Juanmanuel.vilela@fda.hhs.gov).

**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.

**Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR Part 516 (OMB Control Number 0910-0620)—Extension**

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) amended the Federal Food, Drug, and

Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats), as well as uncommon diseases in major animal species.

The MUMS Act created three new sections in the FD&C Act (sections 571, 572, and 573 (21 U.S.C. 360ccc-1, and 360ccc-2)). The final rule (72 FR 69108, December 6, 2007) (the December 2007 final rule) implements section 572 of the FD&C Act that provides for an index of legally marketed unapproved new animal drugs for minor species. Participation in any part of the MUMS program is optional so the associated paperwork only applies to those who choose to participate. The December 2007 final rule specifies, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index as well as the annual reporting requirements for index holders.

Under the new subpart C of part 516 (21 CFR part 516), § 516.119 provides requirements for naming a permanent-resident U.S. agent by foreign drug companies, and § 516.121 provides for informational meetings with FDA.

Section 516.123 provides requirements for requesting informal conferences regarding Agency administrative actions and § 516.125 provides for investigational use of new animal drugs intended for indexing. Provisions for requesting a determination of eligibility for indexing can be found under § 516.129 and provisions for subsequent requests for addition to the index can be found under § 516.145. A description of the written report required in § 516.145 can be found under § 516.143. Under § 516.141 are provisions for drug companies to nominate a qualified expert panel as well as the panel's recordkeeping requirements. Section 516.141 also calls for the submission of a written conflict of interest statement to FDA by each proposed panel member. Index holders are able to modify their index listing under § 516.161 or change drug ownership under § 516.163. Requirements for records and reports are under § 516.165.

In the **Federal Register** of December 3, 2010 (75 FR 75481), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

*Description of Respondents:* Pharmaceutical companies that sponsor new animal drugs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
516.119 .....	2	1	2	1	2
516.121 .....	30	2	60	4	240
516.123 .....	3	1	3	8	24
516.125 .....	2	3	6	20	120
516.129 .....	30	2	60	20	1,200
516.141 .....	20	1	20	16	320
516.143 .....	20	1	20	120	2,400
516.145 .....	20	1	20	20	400
516.161 .....	1	1	1	4	4
516.163 .....	1	1	1	2	2
516.165 .....	10	2	20	8	160
Total .....					4,872

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	No. of record-keepers	Annual frequency per recordkeeper	Total annual records	Hours per recordkeeper	Total hours
516.141 .....	30	2	60	0.5	30
516.165 .....	10	2	20	1	20
Total .....					50

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

Dated: February 18, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-4219 Filed 2-24-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0623]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Cosmetic Registration Program

**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 March 28, 2011.

**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: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0027. Also include the FDA docket number found in brackets in the heading of this document.

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

#### Voluntary Cosmetic Registration Program—21 CFR Parts 710 and 720 (OMB Control Number 0910-0027)—Revision

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides FDA with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the FD&C Act (21 U.S.C.

361) or misbranded under section 602 of the FD&C Act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, the Agency has developed the Voluntary Cosmetic Registration Program (VCRP).

In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the Agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." The term "Form FDA 2511" refers to both the paper and electronic versions of the form. The electronic version of Form FDA 2511 is available on FDA's VCRP Web site at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm>. FDA's online registration system, intended to make it easier to participate in the VCRP, was made available industrywide on December 1, 2005. The Agency strongly encourages electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility will receive confirmation of electronic registration, including a registration number, by e-mail, usually within 7 business days. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

In part 720 (21 CFR part 720), FDA requests that firms that manufacture, pack, or distribute cosmetics file with the Agency an ingredient statement for each of their products. Ingredient statements for new submissions (§§ 720.1 through 720.4) are reported on Form FDA 2512, "Cosmetic Product Ingredient Statement," and on Form FDA 2512a, a continuation form.

Amendments to product formulations (§ 720.6) also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, "Notice of Discontinuance of Commercial Distribution of Cosmetic Product Formulation" (§§ 720.3 and 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA's online filing system is available on FDA's VCRP Web site at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm>. The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512. The Agency strongly encourages electronic filing of Form FDA 2512 because it is faster and more convenient. A filer will receive confirmation of electronic filing by e-mail.

FDA places cosmetic product filing information in a computer database and uses the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, voluntary filings provide FDA with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. The information also is used in defining and planning analytical and toxicological studies pertaining to cosmetics.

Information from the database is releasable to the public under FDA compliance with the Freedom of Information Act. FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry.

In the **Federal Register** of December 15, 2010 (75 FR 78257), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter, containing multiple comments in response to the notice.

(Comment 1) One comment was generally supportive of the necessity of the information collection and its practical utility.