Application No.	Drug	Applicant
ANDA 76–476	Benazepril HCl Tablets, 5 mg, 10 mg, 20 mg, and 40 mg	Mylan Pharmaceuticals, Inc.
ANDA 76–489	Anagrelide HCl Capsules, 0.5 mg and 1 mg	Roxane Laboratories, Inc.
ANDA 77–249	Oxandrolone Tablets USP, 2.5 mg and 10 mg	Do.
ANDA 77–445	Polyethylene Glycol 3350 Powder for Oral Solution	Teva Pharmaceuticals USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454
ANDA 77–648	Zonisamide Capsules, 25 mg, 50 mg, and 100 mg	Roxane Laboratories, Inc.
ANDA 78–026	Paroxetine Tablets USP, 10 mg, 20 mg, 30 mg, and 40 mg	Do.
ANDA 81–008	Strifon Forte DSC (chlorzoxazone tablets USP), 500 mg	Ferndale Laboratories, 780 West 8th Mile Rd., Ferndale, MI 48220
ANDA 81–095	Acetaminophen, Aspirin, and Codeine Phosphate Capsules, 150 mg/180 mg/15 mg	Mikart, Inc., 1750 Chattahoochee Ave., Atlanta, GA 30318
ANDA 83–283	Isoproterenol HCl Injection USP, 0.02 mg/mL	Hospira, Inc.
ANDA 83–838	Promethazine HCl Injection USP	Do.
ANDA 84–074	Bethanechol Chloride Tablets USP, 25 mg	Lannett Co., Inc., 9000 State Rd., Philadelphia, PA 19136
ANDA 84–702	Bethanechol Chloride Tablets USP, 5 mg	Do.
ANDA 84–712	Bethanechol Chloride Tablets USP, 10 mg	Do.
ANDA 84–735	Apresazide (hydralazine HCl and hydrochlorothiazide) Capsules, 25 mg/25 mg	Novartis Pharmaceuticals Corp.
ANDA 84–810	Apresazide (hydralazine HCl and hydrochlorothiazide) Capsules, 50 mg/50 mg	Do.
ANDA 86–366	Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL	Roxane Laboratories, Inc.
ANDA 87–563	Quibron-T/SR (theophylline) Extended-Release Tablets, 300 mg	Monarch Pharmaceuticals, Inc.
ANDA 88–126	Aminophylline Oral Solution USP, 105 mg/5 mL	Roxane Laboratories, Inc.
ANDA 88–656	Quibron-T (theophylline) Tablets, 300 mg	Monarch Pharmaceuticals, Inc.
ANDA 89–650	Lidocaine HCl and Epinephrine Injection USP	Hospira, Inc.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 18, 2009.

Dated: April 30, 2009.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E9–11628 Filed 5–18–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Survey of Refugees (Form ORR–9).

OMB No.: 0970–0033.

Description: The Annual Survey of Refugees collects information on the social and economic circumstances of a random sample of refugees, Amerasians, and entrants who arrived in the United States in the five years prior to the date of the survey. The survey focuses on the refugees training, labor force participation, and welfare utilization rates. Dates are segmented by region of origin, State of resettlement, and number of months since arrival. From the responses, the Office of Refugee Resettlement reports on the economic adjustment of refugees to the American economy. These data are used by Congress in its annual deliberations for refugee admissions and funding and by program managers in formulating policies for the future direction of the Refugee Resettlement Program.

Respondents: Refugees, entrants, Amerasians, and Havana parolees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–9 Annual Survey of Refugees	2,000	1	0.63	1,253.20
Request for Participation Letter	2,000	1	0.04	80

Estimated Total Annual Burden Hours: 1,333.20

Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

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, *Fax:* 202–395–7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: May 14, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–11606 Filed 5–18–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0075]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

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 (the PRA).

DATES: Fax written comments on the collection of information by June 18, 2009.

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, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0437. 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 (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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.

Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting—21 CFR Part 803 (OMB Control Number 0910–0437)—Extension

Section 519(a)(1) of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(a)(1)) requires every manufacturer or importer to report ''whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices: (A) May have caused or contributed to a death or serious injury, or (B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur * * *.''

Section 519(b)(1)(A) of the act requires ''whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.''

Section 519(b)(1)(B) of the act requires ''whenever a device user facility receives or otherwise becomes aware of: (i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility * * *, shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.''

Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems. Information from these reports will be used to evaluate risks associated with medical devices which will enable FDA to take appropriate regulatory measures in protection of the public health under section 519 of the act. Thus FDA is requesting approval for these information collection requirements which are being implemented under part 803 (21 CFR part 803).

Respondents to this collection of information are businesses or other for profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

In the **Federal Register** of February 25, 2009 (74 FR 8547), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one non-related PRA comment that did not require a response.

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