sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

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

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
316.10, 316.12, and 316.14	3	1	3	130	390
316.20, 316.21, and 316.26	138	2.0	276	130	35,880
316.22	22	1	22	2	44
316.27	5	1	5	4	20
316.30	500	1	500	2	1,000
316.36	.2	3	.6	15	9
Total					37,343

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

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 13 years, that 138 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (§§ 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: February 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3860 Filed 2–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0198]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requirements for Medicated Feed Mill License

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Requirements for Medicated Feed Mill License'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47331), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0337. The approval expires on December 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: February 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3861 Filed 2–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

Proposed Project: Evaluation of the Implementation and Outcomes of the Maternal and Child Health Bureau's National Healthy Start Program—NEW

HRSA's Maternal and Child Health Bureau is planning to conduct a survey to collect information concerning Healthy Start, a community-based initiative, to understand how Healthy Start services are expected to change local health care systems and service delivery and ultimately affect maternal and child health outcomes. The purpose of the survey is to collect consistent and comprehensive information across current grantees about their Healthy Start program, its organizational configuration, community context, and the extent to which the program components address service needs and contribute to grantees meeting their Healthy Start goals. A two-part survey consisting of a mail component followed by a telephone follow-up is proposed. The mail survey will focus on obtaining descriptive and quantitative data that is currently not available. The phone survey will be used to obtain grantee assessments of program achievements, factors that facilitated their achievements, and challenges that they faced.

Data collection will cover information on the five service components (case management, health education, outreach, perinatal depression screening, and interconceptional care), and the four systems-building components (consortium, collaboration with Title V, local health systems action plan, and sustainability plan) that comprise the Healthy Start program. Data gathered from the survey will be used to provide HRSA the information necessary to assess the grantees' achievement of three core Healthy Start program goals: (1) Reduced racial and ethnic disparities in access to and utilization of health services; (2) improved local health care system; and (3) increased consumer or community voice in health care decisions. The survey will provide information that is currently unavailable from the service delivery and performance measure data. Based on the data collected in this survey, the National Evaluator will conduct cross-site analyses.

The estimated burden on respondents is as follows:

Respondents	Number of respondents	Hours per respondent	Total hour burden
Grantees	96	3	288

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 13, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–3862 Filed 2–23–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: March 30, 2004, 9 a.m.–5 p.m.; March 31, 2004, 8:30 a.m.–3 p.m.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814, (301) 897–9400.

Status: The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start initiative and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Disparities in Infant Mortality, Low Birth Weight, and The Healthy Start Program and Evaluation. Agenda items are subject to change as priorities are further determined.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr.P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–6327.

Dated: February 13, 2004.

Tina Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–3863 Filed 2–23–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857; (301) 443–6593.