

Project LAUNCH

Proposed Revision to OMB Control No. 0970-0373

Appendix A – 60-Day Federal Register Notice

Posted: February 7, 2011

Along with comments, respondents should provide their name, their title/ position, contact information (e.g., telephone number and/or e-mail address), name and address of company or other entity and type of company or entity (e.g., carrier, exporter, importer, trade association, etc.).

Responses to the NOI will help the Commission ascertain more precisely the impact of slow steaming on U.S. ocean liner commerce, the ocean liner industry, the economy, and the global environment with a view to determining whether, and if so, what additional analyses or action by the Commission may be necessary.

To promote maximum participation, the NOI questions will be made available via the **Federal Register** and on the Commission's Web site at <http://www.fmc.gov> in a downloadable text or pdf file. They can also be obtained by contacting the Commission's Secretary, Karen V. Gregory, by telephone at (202) 523-5725 or by e-mail at secretary@fmc.gov. Please indicate whether you would prefer a hard copy or an e-mail copy of the NOI questions. Non-confidential comments may be sent to secretary@fmc.gov as an attachment to an e-mail submission. Such attachments should be submitted preferably in Microsoft Word or text-searchable PDF.

The Commission anticipates that most filed NOI comments will be made publicly available. The Commission believes that public availability of NOI comments is to be encouraged because it could improve public awareness of the impact of slow steaming on the environment and various segments of the maritime industry. Nevertheless, some commenting parties may wish to include commercially sensitive information as relevant or necessary in their responses by way of explaining

their liner shipping experiences or detailing their responses in practical terms. To help assure that all potential respondents will provide usefully detailed information in their submissions, the Commission will provide confidential treatment to the extent allowed by law for those submissions, or parts of submissions, for which the parties request confidentiality.

By the Commission.
 Karen V. Gregory,
 Secretary.
 [FR Doc. 2011-2482 Filed 2-4-11; 8:45 am]
BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Project LAUNCH Cross-Site Evaluation.

OMB No.: 0970-0373.
Billing Accounting Code (SAC): 418422 (0994426).

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is planning to collect data as part of a cross-site evaluation of a new initiative called Project LAUNCH (Linking Actions for Unmet Needs in Children's Health). Project LAUNCH is intended to promote the healthy development and wellness of children ages birth to eight years. A total of 24 Project LAUNCH grantees are funded to improve coordination among child-serving systems, build infrastructure, and improve methods for providing services. Grantees will also implement a range of public health strategies to

support young child wellness in a designated locality.

Data for the cross-site evaluation of Project LAUNCH will be collected through: (1) Interviews conducted either via telephone or during site-visits to Project LAUNCH grantees, and (2) semi-annual reports that will be submitted electronically on a Web-based data-entry system. Information will be collected from all Project LAUNCH grantees.

During either telephone interviews or the site visits, researchers will conduct interviews with Project LAUNCH service providers and collaborators in States/Tribes and local communities of focus. Interviewers will ask program administrators questions about all Project LAUNCH activities, including: Infrastructure development; collaboration and coordination among partner agencies, organizations, and service providers; and development, implementation, and refinement of service strategies.

As part of the proposed data collection, Project LAUNCH staff will be asked to submit semi-annual electronic reports on State/Tribal and local systems development and on services that children and families receive. The electronic data reports also will collect data about other Project LAUNCH-funded service enhancements, such as trainings, Project LAUNCH systems change activities, and changes in provider settings. Information provided in these reports will be aggregated on a quarterly basis, and reported semi-annually.

Respondents: State/Tribal Child Wellness Coordinator, State/Tribal Wellness Council Members, State ECCS Project Director, Local Child Wellness Coordinator, Local Wellness Council Members, Local Evaluator, and Local Service Providers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Telephone or Site Visit Interview guide	240	1	1.25	300
Electronic Data Reporting: Systems Measures	24	2	4	192
Electronic Data Reporting: Services Measures	24	2	8	384

Estimated Total Annual Burden Hours: 876.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC

20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@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: January 31, 2011.
 Steven M. Hamner,
 Reports Clearance Officer.
 [FR Doc. 2011-2551 Filed 2-4-11; 8:45 am]
BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0601]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

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 9, 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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0152. 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*.

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.

Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225 (OMB Control Number 0910-0152)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document

procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the FD&C Act as to safety and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacture of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer-feeders.

In the **Federal Register** of November, 29, 2010 (75 FR 73101), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN
 [Registered licensed commercial feed mills] ¹

21 CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.42(b)(5) through (b)(8)	1,004	260	261,040	1	261,040
225.58(c) and (d)	1,004	45	45,180	.5	22,590
225.80(b)(2)	1,004	1,600	1,606,400	.12	192,768
225.102(b)(1)	1,004	7,800	7,831,200	.08	626,496
225.110(b)(1) and (b)(2)	1,004	7,800	7,831,200	.015	117,468
225.115(b)(1) and (b)(2)	1,004	5	5,020	.12	602
Total					1,220,964

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

