

Authority: Section 1811 and 1831 of the Social Security Act (42 U.S.C. 1395c and 1395j).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 3, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–13379 Filed 8–24–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0329]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application—Extension

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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the medicated feed mill licensing system.

DATES: Submit written or electronic comments on the collection of information by October 24, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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

Medicated Feed Mill Licensing Application—21 CFR Part 515 (OMB Control Number 0910–0337)—Extension

The Animal Drug Availability Act of 1996 (ADAA), amended section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of medicated feed applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at 21 CFR part 515.

Respondents are expected to be medicated feed manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 515.10(b) | 7 | 1 | 7 | 0.25 | 1.75 |
| 515.11(b) | 100 | 1 | 100 | 0.25 | 25 |
| 515.23 | 25 | 1 | 25 | 0.25 | 6.25 |
| 515.30(c) | 0.15 | 1 | 0.15 | 24 | 3.6 |
| Total Burden Hours | | | | | 36.6 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|----------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 510.305 | 1,070 | 1 | 1,070 | 0.03 | 32.10 |

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

The estimated annual reporting burden on industry is 36.6 hours, as shown in table 1 of this document. Industry estimates it takes about 0.25 hours to submit the application. We estimate 132 original and supplemental applications and voluntary revocations for a total of 33 hours (132 submissions x 0.25 hours). An additional 3.6 hours are added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 36 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated .03 hours for each of approximately 1,070 licensees. Thus, the total burden for recordkeeping requirements is 32.10 hours (1,070 licensees x 0.03 hours).

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Center for Natural Products Research, University of Mississippi; Single Source Cooperative Agreement; Catalog of Federal Domestic Assistance Number 93.103; Request for Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source competing continuation application for the award of a cooperative agreement in fiscal year (FY 2006) to the University of Mississippi (UM) to support the National Center for Natural Products Research (NCNPR), which is located on UM's Campus at Oxford, MS, for up to \$2.3 million for FY06 (direct plus indirect costs combined), the total amount being subject to annual budget appropriations. The funds will provide additional support to the UM's NCNPR for the purpose of promoting more

efficient development and dissemination of natural products research and science and will complement the diverse activities of both the public and private sectors that may become collaborators.

Subject to the availability of Federal funds and successful performance, 4 additional years of support will be available. FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No.93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

II. Eligibility Information

FDA believes that there is compelling evidence that UM is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. UM is a comprehensive research institution with numerous academic programs relevant to FDA's mission and the resources to support the Center for Food Safety and Nutrition's (CFSAN's) areas of interest.

NCNPR, which opened in July 1995, is a division of the Research Institute of Pharmaceutical Sciences of UM's School of Pharmacy. NCNPR was created to bring together an alliance of academia, government, and industry to integrate research, development, and commercialization of potentially useful natural products.

The goal of NCNPR in botanical dietary supplements is to enable safe, effective, and proper use of high quality botanical products by informed professionals and consumers. NCNPR conducts basic and applied multidisciplinary research to discover and develop natural products for use as dietary supplements. NCNPR also maintains a repository of several thousand natural product extracts that are available for screening by collaborators working in other areas.

NCNPR has substantial expertise to carry forward specific discoveries, products, and technologies. Most of the projects to develop promising high priority products or technology are conducted in collaboration with industrial partners or through externally

funded grants and contract. NCNPR is staffed with a highly synergistic mix of full-time research faculty and support staff and employs a number of undergraduate and graduate students and postdoctoral scientists. Together, the faculty, scientists, staff, students, and external collaborators, provide the human resources required to accomplish the research and development goals of NCNPR.

Collaboration between the public and private sector is an efficient means for both FDA and the University to remain current with scientific and technical accomplishments from a natural products research perspective. Harmonizing research activities is but one example of the need for and use of this natural products research knowledge and expertise. The partnership between FDA and UM will provide both the technical and educational expertise necessary for effective mechanisms that will facilitate the movement of new technology and provide direct usefulness to FDA's scientific and enforcement initiatives.

As of October 1, 2003, applicants are required to have a Dun and Bradstreet Number (DUNS) to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, applicants should go to <http://www.grants.gov/RequestaDUNS> or call 1-866-705-5711. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

III. Application and Submission

To comply with the President's Management Agenda, HHS is participating as a partner in the new government-wide *Grants.gov* Web site. Users of *Grants.gov* will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the *Grants.gov* Web site. We encourage applicant submission through *Grants.gov*. If submitted other than electronically, please contact Gladys M. Bohler for guidance (see contact