

these programs currently submit all documentation being requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a net loss, a negative net worth or both must file three quarterly statements. Currently there are approximately 44 MAOs filing quarterly financial statements. The PDPs must also file three unaudited quarterly financial statements. The PACE organizations are required to file 3 quarterly financial statements for the first three years in the program. Additionally, PACE organizations with a net loss, a negative net worth or both must file statements as well.

The information collection request is being revised to include one additional data element for PACE organizations only, Total Subordinated Liabilities. The addition of the new data element will actually reduce the time to analyze the financial standing of PACE organizations because we will no longer have to contact the PACE organizations to establish whether or not the organization's total liabilities calculation includes subordinated debt. *Form Number:* CMS-906 (OCN: 0938-0469); *Frequency:* Annually, Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 648; *Total Annual Responses:* 1,281; *Total Annual Hours:* 428. (For policy questions regarding this collection contact Joe Esposito at 410-786-1129. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: New collection; *Title of Information Collection:* Medicare Enrollment Application for Clinics/ Group Practice and Certain Other Suppliers; *Use:* The primary function of the CMS-855B enrollment application for Clinics, Group Practices and Certain Other Suppliers is to gather information from the organization that tells us what it is, whether it meets certain qualifications to be a health care supplier, where it renders services and information necessary to establish the correct claims payment. The goal of evaluating and revising the CMS-855B enrollment application is to simplify and clarify the information collection without jeopardizing our need to collect specific information. The majority of the revisions are very minor in nature such as spelling and formatting corrections, removal of duplicate fields and instruction clarification for the organization/group. The Sections and Sub-Sections within the form are also being re-numbered and re-sequenced to create a more logical flow of the data

collection. In addition, CMS is adding a data collection for an address to mail the periodic request for the revalidation of enrollment information (only if it differs from other addresses currently collected). Other than the revalidation mailing address described above, new data being collected in this revision package is a checkbox indicating whether or not an organization is wholly owned or operated by a hospital, the inclusion of a new supplier type (Centralized Flu Biller) and information on, if applicable, where the supplier stores its patient records electronically. While the CMS-855B is not a new form, this is considered a new information collection request because we are submitting it to OMB for approval under its own OMB control number. *Form Number:* CMS-855B (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 31,000; *Total Annual Responses:* 31,000; *Total Annual Hours:* 103,000 (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on January 22, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395-6974, *Email:* OIRA_submission@omb.eop.gov.

Dated: December 17, 2012.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2012-N-1181]

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 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 February 19, 2013.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. 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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PIFO-410B, Rockville, MD 20850, 301-796-3794.

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 (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated Feed Mill License Application Using Form FDA 3448 (§ 515.10(b))	20	1	20	.25	5
Supplemental Feed Mill License Application Using Form FDA 3448 (§ 515.11(b))	40	1	40	.25	10
Voluntary Revocation of Medicated Feed Mill License (§ 515.23)	40	1	40	.25	10
Filing a Request for a Hearing on Medicated Feed Mill License (§ 515.30(c))	1	1	1	4	4
Total					29

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of responses per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Labeling (§ 510.305)	950	1	950	0.03	28.5

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

Estimated annual reporting burden on industry is 29 hours as shown in table 1. Industry estimates it takes about 15 minutes (.25) to submit the application. We estimate 100 original and supplemental applications, and voluntary revocations for a total of 25 hours (100 submissions × .25 (15 minutes)). An additional 4 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 28.5 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated .03 hours for each of approximately 950 licensees. Total burden for reporting and recordkeeping would be 57.5 hours.

Dated: December 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-N-0106 (formerly 2002N-0291)]

Baldev Raj Bhutani; Denial of Hearing on Application for Special Termination of Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Baldev Raj Bhutani's application for special termination of debarment under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Mr. Bhutani has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective December 21, 2012.

ADDRESSES: Comments should reference Docket No. FDA-2002-N-0106 and be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire