

Instrument	Number of respondents	Responses/ respondents	Total responses	Hours per response	Total burden hours
Employment Verification Form .....	8,000	1	8,000	.50	4,000
Authorization for Release of Employment Information Form .....	8,000	1	8,000	.10	800
Authorization to Release Information Form .....	8,000	1	8,000	.10	800
Certification Regarding Debarment, Suspension, Disqualification and Related Matters Form .....	8,000	1	8,000	.10	800
Certification of Accreditation Status for School of Nursing Education Programs Form .....	500	1	500	.10	50
Application Checklist and Self-Certification Form .....	8,000	1	8,000	.50	4,000
Total .....			72,500		46,450

The annual estimate of burden for Participants is as follows:

Participant Semi-Annual Employment Verification Form .....	2,300	2	4,600	.5	2,300
Total .....	2,300	2	4,600	.5	2,300

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 22, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0356]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

**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 October 28, 2010.

**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 e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0605. 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, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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.

#### Designated New Animal Drugs for Minor Use and Minor Species; (OMB Control Number 0910-0605)—Extension

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 amended the Federal Food, Drug, and Cosmetic Act to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are "MUMS-designated" by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys,

dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species, for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated paperwork only applies to those sponsors who request and are subsequently granted "MUMS designation." The rule specifies the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees.

Under part 516 (21 CFR part 516), § 516.20 provides requirements on the content and format of a request for MUMS-drug designation, § 516.26 provides requirements for amending MUMS-drug designation, § 516.27 provides provisions for change in sponsorship of MUMS-drug designation, § 516.29 provides provisions for termination of MUMS-drug designation, § 516.30 provides requirements for annual reports from sponsor(s) of MUMS-designated drugs, and § 516.36 provides provisions for insufficient quantities of MUMS-designated drugs. Respondents are pharmaceutical companies that sponsor new animal drugs.

In the **Federal Register** of July 20, 2010 (75 FR 42094), FDA published a 60-day notice requesting public comment on the proposed collection of information. In response, FDA received

one comment that was not responsive to the comment request on the information collection provision.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
516.20	15	5	75	16	1,200
516.26	3	1	3	2	6
516.27	1	1	1	1	1
516.29	2	1	2	1	2
516.30	15	5	75	2	150
516.36	1	1	1	3	3
Total					1,362

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

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug (INAD)/new animal drug application (NADA) reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: September 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0373]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

**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 October 28, 2010.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0541. 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, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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.

#### Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (OMB Control Number 0910-0541)—Extension

As an integral part of its decisionmaking process, FDA is obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions and GRAS petition requests for

exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles. FDA also has eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, FDA has provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to FDA's Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following