

dose-response relationships for physiologic effects and chemosensory effects of mentholated tobacco smoke. FDA also requested information on the impact of menthol on the neurobiology of tobacco dependence and information on dose-related interactions between menthol and nicotine, including on the uptake and metabolism of nicotine and on various consumer perceptions of the product.

FDA has also requested tobacco companies to submit consumer research data and marketing information pertaining to menthol cigarettes. FDA requested consumer research data pertaining to use, cessation, and consumer perception of menthol cigarettes. FDA's request for documents and underlying scientific information related to marketing information includes data and information on

marketing strategies for each brand or subbrand of menthol cigarettes, including strategies targeted to particular demographic groups, strategies aimed at tobacco-naïve consumers, and strategies aimed at recruitment of former tobacco users.

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

| Activity | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Capital Costs |
|---------------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|---------------------|
| Submission of Menthol Documents | 116 | 1 | 116 | 140 | 16,240 | \$1,940 |

The capital costs associated with this collection pertain to the postage for mailing documents in electronic format. Estimating these costs is problematic because the costs would vary depending on the size of the document production (e.g. one binder of documents vs. numerous boxes of paper) and the media type (e.g., compact disk (CD) or digital video disk (DVD)) chosen to submit documents. Currently, we cannot identify how many documents will be submitted per response.

Some sample postage costs are shown for different types of packages:

- 10 CDs in a flat envelope weighing 30 ounces: Approximately \$8 using first class business mail,
- Five-pound parcel containing paper documents: Approximately \$12 using business parcel post mail and delivering to the furthest delivery zone,
- Ten-pound parcel containing paper documents: Approximately \$17 using business parcel mail and delivering to the furthest delivery zone, and
- Fifty-pound parcel containing paper documents: Approximately \$52 using business parcel post mail and delivering to the furthest delivery zone.

This estimate is based upon: (1) Ninety three submissions (80% of 116 submissions) being submitted by mailing an average of 10 CDs per envelope (93 x \$8 = \$744) and (2) Twenty three submissions (20% of the 116 submissions) being submitted by mailing a package of paper documents weighing an average of 50 pounds (23 x \$52 = \$1,196.) Therefore, we estimate the total capital costs associated with this document submission to be \$1,940.

Dated: July 13, 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-0356]

Agency Information Collection Activities; Proposed Collection; 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 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 paperwork associated with designation under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004.

DATES: Submit either electronic or written comments on the collection of information by September 20, 2010.

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: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

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.

Designated New Animal Drugs for Minor Use and Minor Species—21 CFR Part 516 (OMB Control No. 0910-0605)—Extension

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 amended the Federal Food, Drug, and Cosmetic Act (the 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.

FDA estimates the burden of 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 |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 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 |

¹ 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 FDA’s Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug (INAD) and new animal drug (NAD) 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: July 13, 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-0374]

Agency Information Collection Activities; Proposed Collection; Comment Request; Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 reporting requirements contained in existing FDA regulations governing petitions to request an exemption from 100 percent identity testing of dietary ingredients.

DATES: Submit either electronic or written comments on the collection of information by September 20, 2010.

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