4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0716]

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) Act.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, domini.bean@fda.hhs.gov.

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 Number 0910-0605)--Extension

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

Section 516.20 (21 CFR 516.20) provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 (21 CFR 516.26) provides requirements for amending MUMS-drug designation; provisions for change in sponsorship of MUMS-drug designation can be found under § 516.27 (21 CFR 516.27); under § 516.29 (21 CFR 516.29) are

provisions for termination of MUMS-drug designation; under § 516.30 (21 CFR 516.30) are requirements for annual reports from sponsor(s) of MUMS-designated drugs; and under § 516.36 (21 CFR 516.36) are provisions for insufficient quantities of MUMS-designated drugs.

Description of Respondents: Pharmaceutical companies that sponsor new animal drugs.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
516.20; content and format of MUMS request	15	5	75	16	1200
516.26; requirements for amending MUMS designation	3	1	3	2	6
516.27; change in sponsorship	1	1	1	1	1
516.29; termination of MUMS designation	2	1	2	1	2
516.30; requirements for annual reports	15	5	75	2	150
516.36; insufficient quantities	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 our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug/new animal drug application 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: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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