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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Medicare & Medicaid
Services**

[Document Identifier: CMS-437]

**Agency Information Collection
Activities: Proposed Collection;
Comment Request**

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Work Sheet and Supporting Regulations 412.25 and 412.27; *Use:* Certain hospital units are excluded from the Medicare Prospective Payment System (PPS). The exclusion of units is not optional on the part of the provider but is required by section 1886(d)(1)(B) of the Social Security Act. That section excludes psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly individuals under 18 years of age (children's hospitals), and psychiatric and rehabilitation units which are a distinct part of a hospital.

CMS proposes to continue the current process of performing initial verifications and annual reverifications to determine that psychiatric units

continue to comply with the regulatory criteria at 42 CFR 412.25 and 42 CFR 412.27 of the PPS regulations. These regulations state the criteria that distinct part units must meet for exclusion.

If, as a result of the regular survey process a hospital is certified as a psychiatric hospital by the State survey agency (SA), then it automatically satisfies the regulatory criteria for exclusion. Thus, no additional verification is required for psychiatric hospitals. Some verification is needed, however, to ensure that other types of hospitals and units meet the criteria for exclusion.

Consequently, CMS instructed the Fiscal Intermediaries (FIs) and SAs to perform certain verification activities, beginning in October 1983 when PPS was implemented. CMS originally developed the CMS-437 as SA Worksheet for verifying exclusions from PPS for psychiatric units.

Since April 9, 1994, PPS-excluded psychiatric units already excluded from the PPS have met CMS's annual requirement for PPS-exclusion by self-attesting that they remain in compliance with the PPS exclusion criteria. Under the current procedure, all psychiatric units applying for first-time exclusion are surveyed by the SAs. The SAs also perform surveys to investigate complaint allegations and conduct annual sample reverification surveys on 5 percent of all psychiatric units.

The aforementioned exclusions continue to exist and thus CMS proposes to continue to use the Criteria Worksheet, Forms CMS-437 for verifying first-time exclusions from the PPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the PPS-excluded units. *Form Number:* CMS-437 (OMB#: 0938-0358); *Frequency:* Annually; *Affected Public:* Private sector businesses or other for-profits; *Number of Respondents:* 1,333; *Total Annual Responses:* 1,333; *Total Annual Hours:* 333. (For policy questions regarding this collection contact Kelley Leonette at 410-786-6664. 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 at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *February 1, 2011*:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 24, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-30367 Filed 12-2-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2010-N-0597]

**Agency Information Collection
Activities; Proposed Collection;
Comment Request; Index of Legally
Marketed Unapproved New Animal
Drugs for 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 burden hours associated with indexing of legally marketed unapproved new animal drugs for minor species.

DATES: Submit either electronic or written comments on the collection of information by February 1, 2011.

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: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, juanmanuel.vilela@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.

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR Part 516 (OMB Control Number 0910-0620)—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) 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 (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats), as well as uncommon diseases in major animal species.

The MUMS Act added three new sections to the FD&C Act (sections 571, 572, and 573 (21 U.S.C. 360ccc, 360ccc-1, and 360ccc-2, respectively)). The final rule (72 FR 69108, December 6, 2007) implements section 572 of the FD&C Act, which provides for an index of legally marketed unapproved new animal drugs for minor species.

Participation in any part of the MUMS program is optional so the associated

paperwork only applies to those who choose to participate. The final rule specifies, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index as well as the annual reporting requirements for index holders.

Under the new subpart C of part 516 (21 CFR part 516, subpart C), § 516.119 provides requirements for naming a permanent-resident U.S. agent by foreign drug companies, and § 516.121 provides for informational meetings with FDA. Section 516.123 provides requirements for requesting informal conferences regarding agency administrative actions and § 516.125 provides for investigational use of new animal drugs intended for indexing. Provisions for requesting a determination of eligibility for indexing can be found under § 516.129 and provisions for subsequent requests for addition to the index can be found under § 516.145. A description of the written report required in § 516.145 can be found under § 516.143. Under § 516.141 are provisions for drug companies to nominate a qualified expert panel as well as the panel's recordkeeping requirements. This section also calls for the submission of a written conflict of interest statement to FDA by each proposed panel member. Index holders are able to modify their index listing under § 516.161 or change drug ownership under § 516.163. Requirements for records and reports are under § 516.165.

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 BURDEN¹

| 21 CFR Section | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|----------------|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| 516.119 | 2 | 1 | 2 | 1 | 2 |
| 516.121 | 30 | 2 | 60 | 4 | 240 |
| 516.123 | 3 | 1 | 3 | 8 | 24 |
| 516.125 | 2 | 3 | 6 | 20 | 120 |
| 516.129 | 30 | 2 | 60 | 20 | 1,200 |
| 516.141 | 20 | 1 | 20 | 16 | 320 |
| 516.143 | 20 | 1 | 20 | 120 | 2,400 |
| 516.145 | 20 | 1 | 20 | 20 | 400 |
| 516.161 | 1 | 1 | 1 | 4 | 4 |
| 516.163 | 1 | 1 | 1 | 2 | 2 |
| 516.165 | 10 | 2 | 20 | 8 | 160 |
| Total | | | | | 4,872 |

¹ There 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 recordkeeper | Total annual records | Hours per recordkeeper | Total hours |
|----------------|----------------------|-----------------------------------|----------------------|------------------------|-------------|
| 516.141 | 30 | 2 | 60 | 0.5 | 30 |
| 516.165 | 10 | 2 | 20 | 1 | 20 |
| Total | | | | | 50 |

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

Dated: November 29, 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-0266]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer Print Advertisements for Prescription Drugs

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 January 3, 2011.

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-new and title “Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-

796-3792,

Elizabeth.Berbakos@fda.hhs.gov.

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. Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drug—(OMB Control Number 0910-New)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

FDA regulations require that an advertisement that makes claims about a prescription drug include a “fair balance” of information about the benefits and risks of the advertised product, in terms of both content and presentation (21 CFR 202.1(e)(5)(ii)). In past research FDA has focused primarily on the risk component of the risk-benefit ratio. In the interest of thoroughly exploring the issue of fair balance, however, the presentation of effectiveness, or benefit, information is equally important.

The FD&C Act requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product’s uses and risks.¹ By its nature, the presentation of this risk information is likely to evoke active trade-offs by consumers, *i.e.*, comparisons with the perceived risks of not taking treatment, and comparisons with the perceived benefits of taking a

treatment.² Since FDA has an interest in fostering safe and proper use of prescription drugs, an activity that engages both risks and benefits, an in-depth understanding of consumers’ processing of this information is central to this regulatory task.

Research and guidance to sponsors on how to present benefit and efficacy information in prescription drug advertisements is limited. For example, “benefit claims,” broadly defined, appearing in advertisements are often presented in general language that does not inform patients of the likelihood of efficacy and are often simply variants of an “intended use” statement. In a content analysis of DTC advertising,³ the researchers classified the “promotional techniques” used in the advertisements. Emotional appeals were observed in 67 percent of the ads while vague and qualitative benefit terminology was found in 87 percent of the ads. Only 9 percent contained data. For risk information, however, half the advertisements used data to describe side-effects, typically with lists of side-effects that generally occurred infrequently.

FDA regulations require that prescription drug advertisements that make (promotional) claims about a product also include risk information in a “balanced” manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. This balance applies to both the front (aka “display”) page of an advertisement, as well as the brief summary page. However, beyond the “balance” requirement limited guidance and research exists to direct or encourage sponsors to present benefit claims that are informative, specific, and reflect clinical effectiveness data.

The purpose of this project is to: (1) Understand how physicians process clinical efficacy information and how

² See Schwartz, L., S. Woloshin, W. Black, et al., “The Role of Numeracy in Understanding the Benefit of Screening Mammography,” *Annals of Internal Medicine*, 127(11), 966-72, 1997.

³ Woloshin, S. and L. Schwartz, “Direct to Consumer Advertisements for Prescription Drugs: What Are Americans Being Told,” *Lancet*, 358, 1141-46, 2001.

¹ For prescription drugs and biologics, the FD&C Act requires advertisements to contain “information in brief summary relating to side effects, contraindications, and effectiveness” (21 U.S.C. 352(n)).