

regulated products, CDRH determines when to publish notifications.

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. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address

how clearly notifications for reducing risks are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of the information in the alert. Subjects will also be asked whether they wish to receive future notifications electronically, as well as how the PHN program might be improved.

The information collected will be used to shape FDA's editorial policy for the PHN and PPHN. Understanding how

target audiences view these publications will aid in deciding what changes should be considered in their content and format, and method of dissemination.

In the **Federal Register** of August 24, 2009 (74 FR 42674), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

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

PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 1701(a)(4)	308	3	924	.17	157

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

Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: October 19, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0497]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications

**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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork associated with abbreviated new animal drug

applications submitted to the Center for Veterinary Medicine, FDA.

**DATES:** Submit written or electronic comments on the collection of information by January 4, 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, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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, 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.

#### Abbreviated New Animal Drug Applications—FD&C Act/Section 512(n)(1) (OMB Control Number 0910-NEW)

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Public Law 100-670). Under Section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to

submit a complete ANADA or to submit information in support of an ANADA for phased review followed by the submission of an Administrative ANADA when FDA finds that all the applicable technical sections for an

ANADA are complete. FDA requests that an applicant accompany ANADAs and requests for phased review of data to support ANADAs with the Form FDA 356v to ensure efficient and accurate processing of information to support

approval of the generic new animal drug.

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

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

FD&C Act Section 512(n)(1)	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
ANADA	356 V	17	1	17	159	2,703
Phased Review with Administrative ANADA	356 V	5	5	25	31.8	795
Total						3,498

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

**ANADA paperwork burden (Section 512(n)(1) of the act) (21 U.S.C. 360b(b)(2)):**

Over the past 5 fiscal years, from October 2003 through September 2008, FDA has received an average of 22 ANADAs per year. FDA estimates that preparing the paperwork required under Section 512 (n)(1) of the act to be contained in an ANADA, whether all of the information is submitted with the ANADA or the applicant submits information for phased review followed by an Administrative ANADA that references that information, will take approximately 159 hours. FDA is estimating that each ANADA that uses the phased review process will have approximately 5 phased reviews per application. Therefore, assuming that 5 respondents will take advantage of the phased review option per year and an average of 5 phased reviews are submitted per application, times 31.8 hours per phased review, equals 795 total hours per year or 159 hours per application.

FDA believes that with time, more sponsors will take advantage of the phased review option, as it provides greater flexibility. Eventually, phased review will increase to the point of being the majority of ANADAs submitted during the course of the year. FDA also estimates that it takes sponsors of ANADAs approximately 25 percent less time to put together the information to support an ANADA than an NADA because they only need to provide evidence of bioequivalence and not the data required in an NADA to support a full demonstration of safety and effectiveness.

**Form FDA 356v:** FDA requests that an applicant fill out and send in with an ANADA and requests for phased review of data to support an ANADAs, a Form FDA 356v to ensure efficient and

accurate processing of information to support the approval of a generic new animal drug.

This notice also refers to previously approved collections of information found in FDA regulations. The collections of information under 21 CFR 514.80, which describes records and reports that are required post approval, have been approved under OMB Control No. 0910-0284.

Dated: October 27, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0521]

**Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for peramivir 200 milligrams (mg)/20 milliliter (mL) (10 mg/mL) single use vial manufactured for BioCryst Pharmaceuticals, Inc. (BioCryst) for intravenous (IV) administration in certain adult and pediatric patients. Peramivir is a drug that is not approved by FDA. FDA is issuing the Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as

requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of peramivir. The Authorization follows the determination by then Acting Secretary of the U.S. Department of Health and Human Services Charles E. Johnson (then Acting Secretary) that a public health emergency exists involving Swine Influenza A (now known as “2009-H1N1 Influenza”) that affects, or has the significant potential to affect, national security. The determination has been renewed. On the basis of such determination, the Secretary declared an emergency justifying the authorization of the emergency use of the antiviral peramivir, accompanied by emergency use information, subject to the terms of any authorization issued under the act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document. The notice of the declaration of the Secretary is announced elsewhere in this issue of the **Federal Register**.

**DATES:** The Authorization is effective as of October 23, 2009.

**ADDRESSES:** Submit written requests for single copies of the Emergency Use Authorization(s) to the Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

**FOR FURTHER INFORMATION CONTACT:** RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats