products that are comprised of any combination of the following products: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products, and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of August 25, 2009 (74 FR 42900), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 3	43	1	43	24	1,032

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

These burden estimates are based on the number of applications FDA received over the past 2 fiscal years.

Dated: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5749 Filed 3–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0497]

Agency Information Collection Activities; Submission for Office and Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

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 April 16, 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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title "Abbreviated New Animal Drug Application." 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., P150–400B, 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.

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.

In the **Federal Register** of November 2, 2009 (74 FR 56643), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 512(n)(1) of the FD&C Act	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
ANADA	356v	17	1	17	159	2703
Phased Review With Administrative ANADA	356v	5	5	25	31.8	795
Total						3498

[1] 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 document 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: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5747 Filed 3–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–P–0318]

Determination That CERNEVIT–12 (Multivitamins for Infusion) Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) has determined that CERNEVIT–12, multivitamins for infusion (retinol palmitate corresponding to retinol (Vitamin A) 3500 international units (I.U.), cholecalciferol (Vitamin D_3) 200 I.U., DL alpha-tocopherol 10.2 milligrams (mg) corresponding to alpha-tocopherol (Vitamin E) 11.2 I.U., ascorbic acid (Vitamin C) 125 mg, nicotinamide (Vitamin B_3) 46 mg, dexpanthenol 16.15 mg corresponding to pantothenic acid (Vitamin B_5) 17.25 mg, pyridoxine hydrochloride 5.5 mg corresponding to pyridoxine (Vitamin B_6) 4.53 mg, riboflavin sodium phosphate 5.67 mg corresponding to riboflavin (Vitamin B_2) 4.14 mg, cocarboxylase tetrahydrate 5.8 mg corresponding to thiamine (Vitamin B_1) 3.51 mg, folic acid 414 micrograms (mcg), D-biotin 60 mcg, and cyanocobalamin (Vitamin B_{12}) 5.5 mcg), (hereinafter CERNEVIT–12 (multivitamins for infusion)), was withdrawn from sale for reasons of safety or effectiveness. FDA therefore will not accept or approve abbreviated new drug applications (ANDAs) for CERNEVIT–12 (multivitamins for infusion).

FOR FURTHER INFORMATION CONTACT: Nancy Hayes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6354, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law No. 98–417 (the 1984 Amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 Amendments include what is now section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)) (the act), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which generally is known as the "Orange Book." Under FDA regulations (part 314 (21 CFR part 314)), drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA (§ 314.162(a)(1)) or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162(a)(2)).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA