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.

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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

that refers to that listed drug may be approved. FDA may not approve an ANDA that references a listed drug that the agency has determined was withdrawn for reasons of safety or effectiveness (§ 314.127(a)(11)).

CERNEVIT–12 (multivitamins for infusion) is the subject of NDA 20–924, held by Baxter Health Corp. (Baxter). FDA approved the NDA on April 6, 1999, as an application under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)), relying in part upon literature and the agency's prior findings of safety and efficacy for a listed parenteral multivitamin drug product. CERNEVIT–12 (multivitamins for infusion) is indicated as a daily multivitamin maintenance dosage for adults and children age 11 years and older receiving parenteral nutrition, and for situations in which administration by the intravenous route is required.

Adult parenteral multivitamin drug products were reviewed for efficacy under the Drug Efficacy Study Implementation (DESI) program. Under this program, implemented in response to the 1962 amendments to the act requiring demonstration of effectiveness (The Kefauver-Harris Amendments, Public Law No. 87–781 (1962)), the National Academy of Sciences-National Research Council (NAS-NRC) undertook a study of some 4,000 drug formulations for the express purpose of assessing the efficacy of the products. Upon consideration of the findings and recommendations of the NAS-NRC, FDA set forth in the **Federal Register** its conclusions and assessment of whether and under what circumstances a drug product is considered "effective" for use as required by the act.

In the initial DESI notice of July 27, 1972, addressing parenteral multivitamin preparations, FDA announced its conclusion that parenteral multivitamin preparations as then formulated lacked substantial evidence of effectiveness because they did not contain certain essential vitamins, or they contained certain vitamins in doses that were too high or too low (37 FR 15027, July 27, 1972). Because of the critical medical importance of these preparations and the lack of alternative drug products, FDA notified manufacturers and distributors of parenteral multivitamin products in December 1972 that the agency would allow these products to remain on the market pending the development and testing of new formulations and the resolution of complex technical and medical issues (37 FR 26623, December 14, 1972).

On September 17, 1984, FDA announced the parenteral multivitamin formulations the agency had determined to be effective and the conditions for marketing those products (49 FR 36446, September 17, 1984). The agency subsequently modified the conditions for marketing an effective adult parenteral multivitamin drug product in 2000 (65 FR 21200, April 20, 2000). In that "upgrade" notice, FDA announced several changes to the product formulation including increases in the dosage amounts of Vitamins B_1, B_6, C, and folic acid, and amended portions of the "Conditions for Marketing and Approval" for parenteral multivitamin products set forth in the September 17, 1984, notice to reflect the changes (Id. at 21201).

In the **Federal Register** of August 18, 2003, FDA announced that it was withdrawing approval of NDA 20–924 in response to Baxter's withdrawal request dated December 18, 2002 (68 FR 49481, August 18, 2003). As a result, CERNEVIT–12 (multivitamins for infusion) was moved to the "Discontinued Drug Product List" section of the Orange Book.

Strides Arcolab Limited submitted a citizen petition under § 314.161(b) of the regulations (Docket No. FDA–2009–P–0318) requesting that FDA determine whether the NDA for CERNEVIT–12 (multivitamins for infusion) had been withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined that CERNEVIT–12 (multivitamins for infusion) was withdrawn from sale for reasons of safety or effectiveness.

Specifically, we have carefully reviewed our files for records concerning the withdrawal of CERNEVIT–12 (multivitamins for infusion), including the NDA file for this product. We also have independently evaluated relevant literature and data for possible postmarketing adverse event reports. Agency records did not contain any clinical reviews describing safety issues associated with CERNEVIT–12 (multivitamins for infusion), and postmarketing safety reports did not raise any safety concerns.

FDA has determined, however, that CERNEVIT–12 (multivitamins for infusion) was not reformulated to comply with the April 20, 2000, **Federal Register** upgrade notice before it was withdrawn from the market. As described in that notice, adult parenteral multivitamin drug products must contain higher doses of Vitamins B_1, B_6, C, and folic acid than the dosages contained in CERNEVIT–12 (multivitamins for infusion) (65 FR 21201).

Because CERNEVIT–12 (multivitamins for infusion) is not in compliance with current FDA standards for adult parenteral multivitamin drug products, the agency has determined under § 314.161 that CERNEVIT–12 (multivitamins for infusion) was withdrawn from sale for reasons of safety or efficacy. (57 FR 17950 at 17956, April 28, 1992) ("if the NDA or ANDA holder fails to comply with [the DESI upgrade] notice, the NDA or ANDA product is not considered to be approved for effectiveness and cannot be a listed drug"). The Discontinued Drug Product List delineates, among other items, products that have been discontinued from marketing for reasons other than safety or effectiveness. Therefore, CERNEVIT–12 (multivitamins for infusion) will be removed from the Discontinued Drug Product List section of the Orange Book (§ 314.162(a)(2)). In addition, FDA will not accept or approve ANDAs that refer to CERNEVIT–12 (multivitamins for infusion) (21 CFR 314.127(a)(11)).

Dated: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will