TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,920	1	1,920	.30	576

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

The approaches and wording options for qualified health claims of central interest to the agency requires a complex experimental design. To ensure adequate power to identify differences, the minimum cell size is 60 participants. This will be sufficient to identify small to medium effects (i.e., r =.15 to .30) for all main effects and first order interactions with power = (1 – beta), well in excess of .80 at the .05 significance level.

Dated: November 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28196 Filed 11–7–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002P–0431]

Determination That Delcobese (Amphetamine Adipate, Amphetamine Sulfate, Dextroamphetamine Adipate, Dextroamphetamine Sulfate) Tablets and Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets and capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for generic versions of Delcobese tablets and capsules.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 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) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under 314.161(a)(1) of the act (21 CFR 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 does not refer to a listed drug.

Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets (1.25 milligrams (mg), 2.5 mg, 3.75 mg, 5 mg) were the subject of approved ANDA 83–563. Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) capsules (1.25 mg, 2.5 mg, 3.75 mg, 5 mg) were the subject of approved ANDA 83–564. Both ANDAs were submitted by Delco Chemical Co., but ownership was later transferred to Lemmon Co. Delcobese tablets and capsules were labeled for the following indications: (1) Narcolepsy; (2) behavioral syndrome characterized by hyperactivity, distractability, and impulsiveness in children (currently commonly known as attention deficit hyperactivity disorder or ADHD); and (3) exogenous obesity. Prior to Delcobese's discontinuation, FDA proposed to remove the exogenous obesity indication from the labeling of all drug products containing an amphetamine, including Delcobese products, and offered the application holders an opportunity for hearing (44 FR 41552, July 17, 1979). That notice is still pending. While it is pending, the exogenous obesity indication may not be approved for ANDAs relying on Delcobese tablets or capsules as their listed drug (21 CFR 314.127(a)(9)).

On February 22, 1985, Lemmon Co. notified FDA that Delcobese capsules had not been manufactured since March 1984. On June 4, 1990, FDA requested that Lemmon Co. withdraw ANDAs 83–563 and 83–564 because the marketing of both Delcobese capsules and tablets had been discontinued. On February 24, 1993, Lemmon Co. requested the withdrawal of ANDAs 83–563 and 83–564. Accordingly, FDA withdrew approval of the applications in a **Federal Register** notice (58 FR 27737, May 11, 1993). Delcobese was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

In a citizen petition submitted under 21 CFR 10.30 dated September 20, 2002 (Docket No. 02P–0431), as amended by a letter dated October 23, 2002, Sonnenschein Nath & Rosenthal requested that FDA determine whether Delcobese tablets and capsules were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Delcobese tablets and capsules were not withdrawn from sale for reasons of safety or effectiveness. The petitioners identified no data or other information suggesting that Delcobese tablets and capsules were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant data, including postmarketing adverse event reports, but

has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness. Finally, an NDA for a similar amphetamine/dextroamphetamine salt combination was recently approved after the product was found to be safe and effective for the treatment of ADHD.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined above, Delcobese tablets and capsules, approved under ANDAs 83–563 and 83–564, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Delcobese tablets and capsules in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. As a result, ANDAs that refer to Delcobese tablets and capsules may be approved by the agency for appropriate indications.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28193 Filed 11–7–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0498]

Compliance Program Guidance Manual 7371.009; Bovine Spongiform Encephalopathy/Ruminant Feed Ban Inspections; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance program guidance manual (CP) entitled ''Bovine Spongiform Encepholopathy/Ruminant Feed Ban Inspections.'' This CP is intended to assist investigators in determining compliance with the FDA regulation prohibiting the use of specified animal proteins in ruminant feeds (21 CFR 589.2000). The purpose of this regulation is to prevent the establishment and/or amplification within the United States of bovine spongiform encephalopathy (BSE), a fatal degenerative nerve disease of cattle.

DATES: Submit written or electronic comments on the CP at any time.

ADDRESSES: Submit written requests for single copies of the CP to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Copies of the CP also may be downloaded to a personal computer with access to the Internet. The CVM home page includes a link to the CP and may be accessed at *http://www.fda.gov/cvm*. Submit written comments on the CP to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:///www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this compliance program: Neal Bataller, Center for Veterinary Medicine, HFV–230, Food and Drug Administration, 7500 Standish Pl., Rm. E441, Rockville, MD 20855, 301–827–0163, e-mail: *nbatalle@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On August 4, 1997, the ruminant feed ban regulation in § 589.2000 (21 CFR 589.2000) became effective. This regulation prohibits the use of certain proteins derived from mammalian tissues in the feeding of ruminant animals. The regulation is intended to prevent the establishment and/or amplification within the United States of BSE, a fatal degenerative nerve disease of cattle.

BSE is the bovine form of a group of uniformly fatal neurological diseases known as transmissible spongiform encephalopathies (TSEs). BSE appears to be spread through the feeding to cattle of protein derived from TSE-infected animal tissues. Specifically, epidemiologic evidence gathered in the United Kingdom suggests an association between BSE and the feeding to cattle of protein derived from sheep infected with scrapie, another TSE. BSE represents a public health concern based on the possible connection between BSE and a form of human TSE, new variant Creutzfeldt-Jacob disease (nv-CJD), that is believed to have resulted from people eating ruminant tissues infected with the BSE agent. BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected. BSE has not been diagnosed in the United States.

The regulation in § 589.2000 affects renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders. Based on the acute need to prevent the entry and spread of BSE, FDA has set a goal of full compliance with the regulation. This CP is intended to assist in the conduct of inspections to enforce § 589.2000 and thereby minimize risk to human or animal health.

II. Significance of Guidance

This CP is being issued as a level 1 guidance consistent with our good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance and instructions to both agency and state investigators in conducting inspections under § 589.2000 for preventing the introduction and amplication of BSE in the United States. Such guidance is presently not available. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

The CP represents the FDA's current thinking on the subject. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management