DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 7 2007

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Susan Olinger
Corporate Vice President, Regulatory Affairs
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

Re: Docket No. 2006P-0201/CP1

Dear Ms. Olinger:

This letter responds to your citizen petition received on May 11, 2006, requesting that the Food and Drug Administration (FDA) determine whether CEFOTAN (cefotetan disodium for injection), equivalent 1 gram (g) base/vial and 2 g base/vial (new drug application (NDA) 50-588), was voluntarily withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial (NDA 50-588), was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial (NDA 50-588), in the "Discontinued Drug Product List" section of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 443-5537.

Sincerely,

Nam Kim
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

LET 2

2006P-0201

TABLE 1.—ESTIMATED ANNUAL ONE-TIME REPORTING BURDEN[1]—Continued

Claim type	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					189,428

[1] There are no capital costs associated with this collection of information.

Dietary supplement manufacturers will only need to collect information to substantiate their product's nutritional deficiency, structure/function, or general well-being claim if they chose to place a claim on their product's label. Gathering evidence on their product's claim is a one time burden; they collect the necessary substantiating information for their product as required by section 403(r)(6) of the act.

The standard discussed in the guidance for substantiation of a claim on the labeling of a dietary supplement is consistent with standards set by the Federal Trade Commission for dietary supplements and other health related products that the claim be based on competent and reliable scientific evidence. This evidence standard is broad enough that some dietary supplement manufacturers may only need to collect peer-reviewed scientific journal articles to substantiate their claims; other dietary supplement manufacturers whose products have properties that are less well documented may have to conduct studies to build a body of evidence to support their claims. It is unlikely that a dietary supplement manufacturer will attempt to make a claim when the cost of obtaining the evidence to support the claim outweighs the benefits of having the claim on the product's label. It is likely that manufacturers will seek substantiation for their claims in the scientific literature.

The time it takes to assemble the necessary scientific information to support their claims depends on the product and the claimed benefits. If the product is one of several on the market making a particular claim for which there is adequate publicly available and widely established evidence supporting the claim, then the time to gather supporting data will be minimal; if the product is the first of its kind to make a particular claim or the evidence supporting the claim is less publicly available or not widely established, then gathering the appropriate scientific evidence to substantiate the claim will be more time consuming.

FDA assumes that it will take 44 hours to assemble information needed to substantiate a claim on a particular dietary supplement when the claim is widely known and established. We increased this estimated burden from 1 hour per claim to 44 hours per claim based on information received from industry, as noted in our response to comment 1. FDA believes it will take closer to 120 hours to assemble supporting scientific information when the claim is novel or when the claim is pre-existing but the scientific underpinnings of the claim are not widely established. These are claims that may be based on emerging science, where conducting literature searches and understanding the literature takes time. It is also possible that references for claims made for some dietary ingredients or dietary supplements may primarily be found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases, such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body (structure/function final rule (65 FR 1000, January 6, 2000)), FDA estimated that there were 29,000 dietary supplement products marketed in the United States (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims (2,900 x 69 percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667 x 44 hours, 667 x 120 hours, and 667 x 120 hours).

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

Dated: May 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10911 Filed 6–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0201]

Determination That CEFOTAN (Cefotetan Disodium For Injection), Equivalent 1 Gram Base/Vial and 2 Grams Base/Vial, Was 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 CEFOTAN (cefotetan disodium for injection), equivalent 1 gram (g) base/vial and 2 g base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cefotetan disodium for injection, equivalent 1 g base/vial and 2 g base/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5537.

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 typically 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 (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 the "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 (21 CFR 314.162).

Under 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.

CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, is the subject of approved NDA 50–588 held by AstraZeneca Pharmaceuticals LP (AstraZeneca). CEFOTAN (cefotetan disodium for injection) is indicated for the therapeutic treatment of urinary tract infections, lower respiratory tract infections, skin and skin structure infections, gynecologic infections, intra-abdominal infections, and bone and joint infections when caused by susceptible strains of the designated organisms described in the labeling. FDA approved the NDA for CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, on December 27, 1985. Beginning with the October 2006 update, FDA has listed CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, in the "Discontinued Drug Product List" of the Orange Book because AstraZeneca notified FDA that the product was no longer marketed.

B. Braun Medical Inc., submitted a citizen petition dated May 10, 2006 (Docket No. 2006P–0201/CP1), under 21 CFR 10.30, requesting that the agency determine whether CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial (NDA 50–588) was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition (including comments submitted) and reviewing agency records, FDA has determined that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was withdrawn for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA determines that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, 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. ANDAs that refer to CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10959 Filed 6–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2007M–0109, 2007M–0006, 2007M–0007, 2007M–0032, 2007M–0049, 2007M–0038, 2007M–0058, 2007M–0086, 2007M–0107, 2007M–0084, 2007M–0108]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010, ext. 152.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and