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 × 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 × 44 hours, 667 × 120 hours, and 667 × 120 hours).

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21236 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0628]

Determination That PENTETATE CALCIUM TRISODIUM (Trisodium Calcium Diethylenetriaminepentaacetate) Solution for Intravenous or Inhalation Administration, Equivalent to 1 Gram Base/5 Milliliters (Equivalent to 200 Milligrams Base/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 PENTETATE CALCIUM TRISODIUM (trisodium calcium diethylenetriaminepentaacetate (Ca-DTPA)) solution for intravenous or inhalation administration, equivalent to (EQ) 1 gram (g) base/5 milliliters (mL) (EQ 200 milligrams (mg) base/mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexis Reisin Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6356, Silver Spring, MD 20993–0002, 301–796–3977.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) is the subject of NDA 21–749, held by Hameln Pharmaceuticals GmbH, and initially approved on August 11, 2004. PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) is indicated for treatment of individuals with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination.

In a letter dated June 24, 2010, Hameln Pharmaceuticals GmbH notified FDA that PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Heyl Chemisch-pharmazeutische Fabrik GmbH & Co. KG submitted a citizen petition dated November 26, 2010 (Docket No. FDA–2010–P–0628), under 21 CFR 10.30, requesting that the Agency determine whether PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) 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 PENTETATE CALCIUM TRISODIUM (Ca-DTPA) solution for intravenous or inhalation

administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21227 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0630]

Determination That PENTETATE ZINC TRISODIUM (Zinc Trisodium Diethylenetriaminepentaacetate) Solution for Intravenous or Inhalation Administration, Equivalent to 1 Gram Base/5 Milliliters (Equivalent to 200 Milligrams Base/Milliliter), 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 PENTETATE ZINC TRISODIUM (zinc trisodium diethylenetriaminepentaacetate (Zn-DTPA)) solution for intravenous or inhalation administration, equivalent to (EQ) 1 gram (g) base/5 milliliters (mL) (EQ 200 milligrams (mg) base per mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexis Reisin Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6356, Silver Spring, MD 20993–0002, 301–796–3977.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants 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 FD&C 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) is the subject of NDA 21–751, held by Hameln Pharmaceuticals GmbH, and initially approved on August 11, 2004. PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) is indicated for treatment of individuals with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination.

In a letter dated June 24, 2010, Hameln Pharmaceuticals GmbH notified the FDA that PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Heyl Chemisch-pharmazeutische Fabrik GmbH & Co. KG submitted a citizen petition dated December 6, 2010 (Docket No. FDA–2010–P–0630), under 21 CFR 10.30, requesting that the Agency determine whether PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)), 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 PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If the FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will