TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2017–2018 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3.	400	1	400				1.36	544
2017–2018 Data Collection (Full Service Restaurants)—Completion of Sections 1 and 3.	400	1	400				1.73	692
2017–2018 Data Collection-Completion of Section 2—All Facility Types.	800	1	800				0.5 (30 minutes).	400
2017–2018 Data Collection-Entry Refusals—All Facility Types.				16	1	16	0.08 (5 minutes).	1.28
Total hours							.....	1,637.28

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

II. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. *FDA Food Code.* Available at: *http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm.*

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29065 Filed 12–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0320]

Determination That PFIZERPEN (Penicillin G Potassium) Injection, 1 Million Units/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA) has determined that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn from sale for reasons of safety or effectiveness.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 penicillin G potassium injection, 1 million units/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, 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 (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 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 (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, is the subject of ANDA 60–657, held by Pfizer, Inc., and initially approved on August 30, 1968. ANDA 60–657 is considered the designated reference standard. PFIZERPEN is indicated in the treatment of serious infections caused by susceptible strains of the designated microorganisms in certain conditions such as septicemia, pneumonia, meningitis, anthrax, and listeria.

PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Lachman Consultant Services, Inc., submitted a citizen petition dated May 27, 2008 (Docket No. FDA–2008–P–0320), under 21 CFR 10.30,

requesting that the Agency determine whether PFIZERPEN (penicillin G potassium) Injection, 1 units/vial, and penicillin G potassium injection, 1 million units/vial, had been withdrawn from sale for reasons of safety or effectiveness. Penicillin G potassium Injection, 1 million units/vial, is the subject of ANDA 65–079, held by Sandoz, and approved on August 30, 2002.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn for reasons of safety or effectiveness (this determination also applies to penicillin G potassium injection, 1 million units/vial, ANDA 65–079). The petitioner believes that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn for reasons of safety or effectiveness because it was discontinued due to commercial reasons. We have carefully reviewed our files for records concerning the withdrawal of PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PFIZERPEN (penicillin G potassium) Injection, 1 million units/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 PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, 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: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29034 Filed 12–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Budesonide Extended-Release Tablets; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Budesonide Extended-Release Tablets.'' The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for budesonide extended-release tablets.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1615, Silver Spring, MD 20993–0002, 240–402–7290.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for budesonide extended-release tablets.

New drug application 203634 for UCERIS (budesonide) extended-release tablets, 9 milligrams (mg), was initially approved by FDA in January 2013. FDA is now issuing a draft guidance for industry on BE recommendations for generic budesonide extended-release tablets.

In February 2013, Santarus, Inc., submitted a citizen petition requesting that FDA: (1) Issue an individual BE guidance for budesonide extended-release tablets and (2) refrain from approving any ANDA that identifies UCERIS (budesonide) extended-release tablets as the reference listed drug unless the generic product is shown to be bioequivalent based on appropriate data from a clinical efficacy endpoint study, comparative pharmacokinetic testing, in vitro dissolution testing, and pharmacoscintigraphy studies (Docket No. FDA 2013–P–0127). FDA reviewed the issues raised in the petition and is responding to the petition today in a letter that will be included in the citizen petition docket.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for budesonide extended-release tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the