Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Law Enforcement Officers	Pre-Enrollment Confirmation Email	333	1	1/60	6
Law Enforcement Officers	Biographical Information	333	1	3/60	17
Law Enforcement Officers	Consent form	333	1	5/60	28
Law Enforcement Officers	Traditional anthropometric measurements.	333	1	30/60	167
Law Enforcement Officers	2D and 3D scans	333	1	30/60	167
Total					385

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–05265 Filed 3–15–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–N–2016–4198]

Public Meeting on Patient-Focused Drug Development for Sarcopenia; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Public Meeting on Patient-Focused Drug Development for Sarcopenia'' that appeared in the **Federal Register** of December 14, 2016 (81 FR 90361). The document announced a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Sarcopenia. The location of the meeting has changed and this document provides the updated meeting location.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, FAX: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov*.

In the **Federal Register** of Wednesday, December 14, 2016, in FR Doc. 2016–29998, the following correction is made:

1. On page 90361, in the second column, in the first sentence of the **ADDRESSES** section, ''FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, (Rm. 1503), Silver Spring, MD 20993–0002.'' is corrected to read ''Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903.''

Dated: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05247 Filed 3–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–1676]

Determination that CYANOCOBALAMIN INJECTION, 1 Milligram per Milliliter in a 10 Milliliter 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 or Agency) has determined that CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Elizabeth Trentacost, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 240–402–7736.

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, dosage form, and route of administration 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.

CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, is the subject of ANDA 080557, held by Fresenius Kabi USA (Fresenius), and initially approved on June 20, 1973. CYANOCOBALAMIN INJECTION is indicated for vitamin B_{12} deficiencies due to malabsorption that may be associated with the following conditions: Addisonian (pernicious) anemia; gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacterial overgrowth, and total or partial gastrectomy; fish tapeworm

infestation; malignancy of pancreas or bowel; or folic acid deficiency.

In a letter dated December 21, 2016, Fresenius notified FDA that CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was discontinued over 30 years ago, and Fresenius had concluded that the drug was discontinued for reasons other than safety or effectiveness. Fresenius also conveyed that they currently manufacture and market a 1 milliliter multiple dose vial of the 1 milligram per milliliter concentration.

John R. Rapoza submitted a citizen petition dated June 16, 2016 (Docket No. FDA–2016–P–1676), under 21 CFR 10.30, requesting that the Agency determine whether CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was withdrawn from sale for reasons of safety or effectiveness.

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 CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter 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 drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will list CYANOCOBALAMIN INJECTION, 1 milligram per milliliter in a 10 milliliter 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05246 Filed 3–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances for Rifaximin; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a revised draft guidance for industry on generic rifaximin oral tablets entitled ''Draft Guidance on Rifaximin.'' The revised draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for rifaximin oral 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 comment 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 May 15, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Rifaximin.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more