

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

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-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,

**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 B₁₂ 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