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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Mark Geanacopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 301–796–6925.

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 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, a drug is 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 006146	BENADRYL (diphenhydramine hydrochloride) Injection, 50 milligrams (mg)/milliliter (mL).	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034.
NDA 009486	BENADRYL PRESERVATIVE FREE (diphenhydramine hydrochloride) Injection, 50 mg/mL.	Do.
NDA 017821	FLEXERIL (cyclobenzaprine hydrochloride) Tablets, 5 mg and 10 mg.	Janssen Research & Development, LLC, 920 Rt. 202, Raritan, NJ 08869.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. 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: March 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06726 Filed 3–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1205]

Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the **Federal Register** of January 7, 2013 (78 FR 951). In the notice, FDA requested comments on the public workshop entitled ''Accessible Standardized Medical Device Labeling.'' The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by May 17, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–1205, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. FDA–2012–N–1205. All comments received may be posted

without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Weick-Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5426, 301–796–6089, FAX: 301–847–8510, email: *Mary.Brady@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 7, 2013 (78 FR 951), FDA published a notice of public workshop with a 90-day comment period to request comments on all aspects of the public workshop, including topics outlined in section II of that document (78 FR 951 at 952).

The agency has received a request for an extension of the comment period until May 30, 2013. The request conveyed concern that the current comment period does not allow sufficient time to develop a meaningful or thoughtful response that allows for consideration of presentations by FDA and other stakeholders at the public workshop on April 29 and 30, 2013.

FDA has considered the request and is extending the comment period for the notice of public workshop until May 17, 2013. The agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying consideration of these important issues.

II. Request for Comments

Regardless of attendance at the public workshop, 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 heading of this document. In addition, when responding to specific questions as outlined in section II of the notice of public workshop (78 FR 951 at 952), please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06725 Filed 3–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: NIH Office of Intramural Training & Education Application

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Intramural Training & Education/OIR/OD, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NIH Office of Intramural Training & Education Application. *Type of Information Collection Request:* Revision. *Form Number:* 0925–0299. *Expiration Date:* March 31, 2014. *Need and Use of Information Collection:* The Office of Intramural Training & Education (OITE) administers a variety of programs and initiatives to recruit pre-college through post-doctoral educational level individuals into the National Institutes of Health Intramural Research Program (NIH–IRP) to facilitate develop into future biomedical scientists. The proposed information collection is necessary in order to determine the eligibility and quality of potential awardees for traineeships in these programs. The applications for admission consideration include key areas such as: personal information, eligibility criteria, contact information, student identification number, training program selection, scientific discipline interests, educational history, standardized examination scores, reference information, resume components, employment history, employment interests, dissertation research details, letters of recommendation, financial aid history, sensitive data, future networking contact, travel information, as well as feedback questions about interviews and application submission experiences. Sensitive data collected on the applicants, race, gender, ethnicity, disability, and recruitment method, are made available only to OITE staff members or in aggregate form to select NIH offices and are not used by the admission committee for admission consideration; optional to submit.

Frequency of Response: On occasion. *Affected Public:* Individuals seeking intramural training opportunities and references for these individuals. *Type of Respondents:* students, post-baccalaureates, technicians, graduate students, post-doctorates, references, and alumni. There are no capital costs, operating costs, and/or maintenance costs to report.

The annual reporting burden is displayed in the following table:

Type of respondent	Estimated No. of respondents	Estimated No. of responses annually per respondent	Estimated total annual burden hours	Estimated total annual burden hours
Summer Internship Program in Biomedical Research (SIP)	6,820.0	1.0	1.0	6,820.00
Biomedical Engineering Summer Internship Program (BESIP)	80.0	1.0	1.0	80.00
Post-baccalaureate Training Program (PBT)	1,885.0	1.0	1.0	1,885.00
Community College Summer Enrichment Program (CCSEP)	100.0	1.0	1.0	100.00
Technical Training Program (PBT)	115.0	1.0	1.0	115.00
Graduate Partnerships Program (GPP)—Application (Select Institutional Partnerships)	250.0	1.0	1.0	250.00
Graduate Partnerships Program (GPP)—Registration (Select Institutional Partnerships + Individual Partnership)	140.0	1.0	1.0	140.00
National Graduate Student Research Conference (NGSRC)	800.0	1.0	1.0	800.00