

“[a]nalysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories)” (§ 129.35(a)(3)(iii)). For product water, the regulations also state that bottled water manufacturers will “[a]nalyze such samples by methods approved by the government agency or agencies having jurisdiction” (§ 129.80(g)(3)).

One comment noted that the EPA issued a final rule on February 13, 2013, that established a maximum contaminant level for *E. coli* and stated that *E. coli* is a more specific indicator of fecal contamination and the potential presence of associated pathogen occurrence than fecal coliforms. FDA agrees that *E. coli* is an appropriate indicator of fecal contamination and that the presence of fecal indicators demonstrates the potential for the

presence of fecal pathogens. FDA requires bottled water manufacturers to sample and analyze source water obtained from other than a public water system for total coliform at least once each week. If any coliform organisms are detected, manufacturers must conduct followup testing to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water. Manufacturers must also analyze product water samples at least once a week for total coliform, and, if any coliform organisms are detected, they must conduct followup testing to determine whether any of the coliform organisms are *E. coli*. Product water containing *E. coli* is considered adulterated. Thus, the presence of the fecal indicator *E. coli* is the key factor for determining whether

source water is of a safe, sanitary quality, and whether product water is adulterated. FDA is reviewing the EPA final rule referenced in the comment (National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule, 78 FR 10269; February 13, 2013) to determine what actions, if any, FDA needs to take to respond to the rule.

To the extent that the comments recommended changes to FDA's bottled water regulations, which can only be accomplished by rulemaking, the comments were outside the scope of the four collection of information topics on which the notice requested comments and will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§§ 129.35(a)(3)(i) and 129.80(h)	319 (bottlers subject to source water and finished product testing).	6	1,914	0.08 (5 minutes)	153
§ 129.80(g) and 129.80(h)	95 (bottlers testing finished product only).	3	285	0.08 (5 minutes)	23
§§ 129.35(a)(3)(i) and 129.80(h)	3 (bottlers conducting secondary testing of source water).	5	15	0.08 (5 minutes)	1
§§ 129.35(a)(3)(i) and 129.80(h)	3 (bottlers rectifying contamination)	3	9	0.25 (15 minutes)	2
Total					179

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

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. We therefore conclude that any additional burden and costs in recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for *E. coli* are negligible. We estimate that the labor burden of keeping records of each test is about 5 minutes per test. We also require followup testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. We expect that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about 3 times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs

may find a total coliform positive sample about 3 times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a followup test for *E. coli*.

We expect that recordkeeping for the followup test for *E. coli* will also take about 5 minutes per test. As shown in table 1 of this document, we expect that 3 bottlers per year will have to carry out the additional *E. coli* testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, *E. coli* testing, and source rectification, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0320]

Determination That BENADRYL (diphenhydramine hydrochloride) Injection and Two Other Drug Products Were 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 the three drug products listed in this document were 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 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.

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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