TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Develop documentation process	1	1	1	16	16

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

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not be currently maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. In previous information collection requests, this recordkeeping burden was estimated to be 16 hours. Although FDA estimates that only 1 out of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the one submission per year as zero, FDA has retained its prior estimate of 16 hours for the recordkeeping burden.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 15, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3415 Filed 2–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–C–0098]

Combe, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Combe, Inc., has filed a petition proposing that the color additive regulations be amended to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp.

DATES: Submit written or electronic comments on the petitioner's environmental assessment by March 26, 2008.

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

FOR FURTHER INFORMATION CONTACT: Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1264.

SUPPLEMENTARY INFORMATION: Under section 721e(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), notice is given that a color additive petition (CAP 8C0286) has been filed by Combe, Inc., c/o EAS Consulting Group, LLC, 1940 Duke St., suite 200, Alexandria, VA 22314. The petition proposes to amend the color additive regulations in § 73.2110 *Bismuth citrate* (21 CFR 73.2110) to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 15, 2008.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E8–3416 Filed 2–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0060] (formerly Docket No. 1998D–0021)

Guidance for Industry: Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Container and Closure System Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products,'' dated February 2008. The guidance document provides recommendations to sponsors for using methods other than sterility testing to confirm the integrity of container and closure systems as part of stability testing for sterile biological products, human and veterinary drugs, and

medical devices. The guidance document does not apply to sterility testing methods for product sterility testing prior to release, as container and closure system integrity tests cannot demonstrate a product's initial sterility. The guidance announced in this notice finalizes the draft guidance entitled ''Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products,'' dated January 1998.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of theguidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857; or to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; or to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The guidance may also be obtained by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT:

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210,or

David Hussong, Center for Drug Evaluation and Research (HFD–805), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1228,or

Geetha J. Jayan, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd, Rockville, MD 20850, 240–276–3747, or

Mai Huynh, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Container and Closure System Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products,'' dated February 2008. The guidance document provides information to sponsors who propose using alternative methods to sterility testing to confirm container and closure integrity for sterile biological products, human and veterinary drugs, and medical devices throughout a product's dating period. The guidance document is applicable only to stability testing, a means of confirming expiration dating. The alternatives described in the guidance document are not offered as a replacement for sterility testing prior to product release, as container and closure system integrity tests cannot demonstrate a product's initial sterility.

In the **Federal Register** of January 28, 1998 (63 FR 4272), FDA announced the availability of the draft guidance entitled ''Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products,'' dated January 1998. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. This guidance document was prepared jointly by CBER, CDER, CVM, and CDRH.

The guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance document represents the agency's current thinking on this topic. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 211.166 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 314.70 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR 514.8 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR 814.39 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR 820.75 have been approved under OMB control number 0910–0073.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cdrh/guidance.html*, or *http://www.fda.gov/cvm/guidance/published.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 12, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3487 Filed 2–22–08; 8:45 am]

BILLING CODE 4160–01–S