

Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief; Draft Guidance for Industry and FDA Staff" (1574); (6) "Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes; Draft Guidance for Industry and FDA Staff" (1575); (7) "Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited Output for Aesthetic Purposes; Draft Guidance for Industry and FDA Staff" (1576); (8) "Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation; Draft Guidance for Industry and FDA Staff" (1577); (9) "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation; Draft Guidance for Industry and FDA Staff" (1578); (10) "Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning; Draft Guidance for Industry and FDA Staff" (1579); and/or (11) "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning; Draft Guidance for Industry and FDA Staff" (1580).

Persons interested in obtaining a copy of any or all of the draft guidance documents may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/MedicalDevices/default.htm>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

These 11 draft guidance documents refer to previously approved collections of information found in FDA regulations.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 part 807

(21 CFR part 807), subpart E pertain to premarket submission requirements for any person who intends to market certain medical devices, and have been approved under OMB control number 0910–0120.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate special controls for each of these devices and would exempt six of them from the premarket notification requirements of the act. The proposed rule contains an analysis of the paperwork burden for the proposed rule, including the anticipated reduction in burden for manufacturers who follow the special controls and for manufacturers of the six proposed exempt device types. Consistent with the Paperwork Reduction Act of 1995, we solicit comment on our revised burden estimates.

V. Comments

The agency is specifically interested in comments on the types of claims appropriate for devices included within these 11 classifications and, for the devices that remain subject to premarket review, the data sponsors should submit to support those claims. For example, under the proposed rule, certain transcutaneous electrical stimulators for aesthetic purposes would remain subject to 510(k). The agency is interested in comments on the type of data sponsors should submit to show a transcutaneous electrical nerve stimulator device achieves "aesthetic effects through physical change to the structure of the body" as well as the predicate device does.

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 copies of any mailed comments, except that individuals may submit one 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 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 24, 2010.

Jeffrey Shuren,

Director, Center for Devices and Radiological Health.

[FR Doc. 2010–7634 Filed 4–2–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0100]

Food Additives; Bisphenol A; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of five documents related to FDA's continuing assessment of Bisphenol A (BPA) and soliciting public comments on the four documents prepared by FDA's Center for Food Safety and Applied Nutrition (CFSAN). These documents do not represent an agency opinion or position on BPA, on which an interim update was recently provided. (See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>). Rather, these documents provide perspectives and opinions that are being considered by FDA as it continues its safety assessment of BPA. This action will enable FDA to consider comments from the public in its assessment of BPA for food contact applications.

DATES: Submit written or electronic information and comments by June 4, 2010.

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

FOR FURTHER INFORMATION CONTACT: Francis Lin, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1215.

SUPPLEMENTARY INFORMATION:

I. Background

BPA is a chemical used in certain food contact materials. Uses of BPA were approved by FDA under its food additive regulations in the early 1960s. In recent years, questions have been raised about BPA's safety. On August 14, 2008, FDA delivered its Draft Assessment of BPA for Use in Food Contact Applications (the Draft Assessment) (Ref. 1) to a Subcommittee of FDA's Science Board for external review.

On September 16, 2008, the Subcommittee held a public meeting on BPA as part of its external review

process, after which the Subcommittee wrote and transmitted its report to the FDA Science Board. On October 31, 2008, the Science Board accepted the Subcommittee's report and transmitted it to FDA with suggestions for revising the Draft Assessment and instructions to conduct a more in-depth review of certain relatively recent low-dose studies identified in a draft report, released in April 2008, by the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) (Ref. 2) and included in the final assessment completed by the NTP (Ref. 3).

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has provided a review, as suggested by the Science Board, of the low-dose studies mentioned in the NTP report and issued a memorandum describing that review (Doc. 1).¹ In this review (Doc. 1), CFSAN also describes its review of other relevant studies that were either made available since the publication of the NTP report or suggested by the Science Board for consideration. Five expert, non-FDA, government scientists were requested by FDA to conduct a scientific review of CFSAN's assessment of the low-dose studies. Their reviews are combined and made available in Doc. 2 and, as such, provide perspectives on Doc. 1 that may be helpful as additional context, including

for those who may want to comment on the CFSAN documents.

Based on its initial review of these materials, FDA recently provided an interim update where it expressed "some concern" about the potential effects of BPA on the brain, behavior, and prostate gland of fetuses, infants, and children, consistent with the final NTP report (Ref. 3), and indicated steps it is taking and interim recommendations, to address these concerns (see <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>). FDA also recognized (*id.*), as did the NTP review, substantial uncertainties with respect to the overall interpretation of these studies and their potential implications for human health effects of BPA exposure. These uncertainties relate to issues such as the routes of exposure employed, the lack of consistency among some of the measured endpoints or results between studies, the relevance of some animal models to human health, differences in the metabolism (and detoxification) of and responses to BPA both at different ages and in different species, and limited or absent dose response information for some studies.

In a third document (Doc. 3), CFSAN reviews and summarizes a number of studies of BPA and health that were made available after its assessment of low-dose studies (Doc. 1). Among the additional studies summarized in Doc. 3

is an as yet unpublished study focused on the potential developmental neurotoxicity of dietary BPA in rats (Ref. 4), which was commissioned by the American Chemistry Council and submitted to FDA.

FDA also is making available CFSAN's updated dietary exposure estimate for the food contact uses of BPA in packaging for infant formula, baby and adult foods, and polycarbonate nursing bottles (Doc. 4). Finally, FDA is making available CFSAN's review of available biomonitoring data on BPA (Doc. 5).

At this time, as FDA continues its safety assessment of BPA, we are seeking public comment on the four CFSAN documents (Docs. 1, 3, 4, and 5) that are relevant to this safety assessment. While pre-decisional documents such as these are not required to be made available for public comment, we believe it is appropriate in this case due to the complexity of the scientific issues and the degree of public interest in FDA's scientific assessment of BPA. As we update our assessment, which may include additional peer review, we will consider any public comments received, as well as new scientific findings as they become available. The five documents, which are available in the docket established for this notice, are listed in table 1 of this document.

TABLE 1.

Document No.	Date	Title
1	August 31, 2009	Memorandum from Toxicology Group 1, Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition; HFS-275: "Bisphenol A (CAS RN. 80-05-7): Review of Low-Dose Studies"
2	November 2009	External Governmental Reviewer Comments on Draft Report: "Bisphenol A (CAS RN. 80-05-7): Review of Low-Dose Studies"
3	November 24, 2009	Memorandum from Toxicology Group 1, Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition; HFS-275: "Bisphenol A (CAS RN. 80-05-7): studies added to 'Review of Low Dose Studies' assessment"
4	October 22, 2009	Memorandum from: Chemistry Review Group 1, Division of Food Contact Notifications and Chemistry Team, HFS-275 and Chemistry Review Team, Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition; HFS-255: "Exposure to Bisphenol A (BPA) for infants, toddlers and adults from the consumption of infant formula, toddler food and adult (canned) food"
5	November 16, 2009	Memorandum from: Regulatory Group 2, Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, HFS-275: "Summary of Bisphenol A Biomonitoring Studies"

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written

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

¹ See table 1 of this document for a description of Document (Doc.) numbers 1 through 5.

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.regulations.gov>.

IV. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to non-FDA Web sites after this document publishes in the **Federal Register**.

1. Draft Assessment of Bisphenol A for Use in Food Contact Applications (August 14, 2008). Accessible at: <http://www.fda.gov/food/foodingredientspackaging/ucm166145.htm>.

2. Draft NTP Brief on Bisphenol A, April 14, 2008. Accessible at: http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf.

3. National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction. NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. NIH Publication No. 08-5994. September 2008. Accessible at: <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf>.

4. WIL Research Laboratories, LLC. A Dietary Developmental Neurotoxicity Study of Bisphenol A in Rats (WIL-186056), September 30, 2009.

Dated: March 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-7511 Filed 4-2-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0343]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 9 on Tablet Friability General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Q4B Evaluation and Recommendation of

Pharmacopoeial Texts for Use in the ICH Regions; Annex 9: Tablet Friability General Chapter." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Tablet Friability General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This guidance is in the form of an annex to the core guidance on the Q4B process entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions" (core ICH Q4B guidance).

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and

Research (HFD-003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993-0002, 301-796-1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of August 14, 2009 (74 FR 41144), FDA published a