Systems for Over-the-Counter Use.'' Submit either electronic or written comments by May 7, 2014.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patricia Bernhardt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5654, Silver Spring, MD 20993–0002, 301–796–6136.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 7, 2014 (79 FR 829), FDA published a notice announcing the availability of the draft guidance entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' Interested persons were invited to submit comments by April 7, 2014. At this time the Agency is extending the comment period until May 7, 2014, to continue to receive public comments. Comments submitted to the docket will assist in identifying issues to be addressed in the finalized guidance document.

II. Request for Comments

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. 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: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07899 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry, researchers, patient groups, and FDA staff entitled ''Meetings With the Office of Orphan Products Development.'' This draft guidance provides recommendations to industry, researchers, patient groups, and other stakeholders (collectively referred to as ''stakeholders'') interested in requesting a meeting with FDA's Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. This draft guidance document is intended to assist these groups with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance or proposed collection of information by June 9, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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. Identify comments with the docket number found in brackets in the heading of this document. OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: James Bona, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, researchers, patient groups, and FDA staff entitled ''Meetings With the Office of Orphan Products Development.'' Each year, OOPD staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or HUD designation requests, OOPD grant programs, or other rare disease issues. These meetings can be ''informal'' or ''formal'' and help build a common understanding on FDA's thoughts on orphan products, which include drugs, biological products, devices, or medical foods. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate. This guidance is intended to provide consistent procedures to promote well managed meetings between OOPD and stakeholders.

Topics addressed in this guidance include: (1) Clarification of what constitutes an ''informal'' or ''formal'' meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on meetings with OOPD. 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

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques and other forms of information technology, when appropriate.

Title: Draft Guidance for Industry, Researchers, Patients Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development.

Description: FDA is issuing a draft guidance on the procedures for requesting meetings with OOPD on issues related to orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. The draft guidance describes procedures for requesting, scheduling, conducting, and documenting such meetings.

The draft guidance describes three collections of information: (1) The submission of a meeting request (for informal and formal meetings), (2) the submission of a meeting package (for formal meetings), and (3) the submission of draft meeting minutes (for formal and certain informal meetings). These collections of information will be used by the Agency to schedule and prepare for meetings on the issues described previously in this document and will provide for more productive meetings with stakeholders. This draft guidance refers to previously approved collections of information found in FDA regulations. Agency regulations at part 316 (21 CFR part 316) describe information that should be submitted in support of an orphan drug designation request. The information collection provisions of part 316 have been approved under OMB control number 0910–0167. Agency regulations at § 814.102 (21 CFR 814.102) describe information that should be submitted in support of a HUD designation request. The information collection provisions of § 814.102 have been approved under OMB control number 0910–0332.

A. Request for a Meeting

Under the draft guidance, a stakeholder interested in meeting with OOPD should submit a meeting request:

- For specific designation requests or grant applications, by emailing the identified point of contact for the designation request or grant application with the subject heading ''Meeting Request''; or
- For other issues, by emailing the general OOPD inbox at *orphan@fda.hhs.gov* with the subject heading ''Meeting Request'' or by emailing the point of contact for each OOPD Program Area listed in the ''Contact FDA'' section of the OOPD's Web site (*http://www.fda.gov/orphan*), again with the subject heading ''Meeting Request.'' In the draft guidance, FDA recommends that the meeting request, at a minimum, include (1) a brief statement of the meeting purpose, (2) whether the stakeholder prefers an informal or formal meeting, (3) suggested dates and times for the meeting, (4) preferred format of the meeting, and (5) the email address(es) to which OOPD should send a response to the meeting request (if different from the email address from which the request was sent) and telephone number for the primary contact for the stakeholder. Before scheduling a meeting, OOPD may ask the stakeholder for more information about the proposed meeting to help determine whether an informal or formal meeting is most appropriate and who from OOPD should attend. For informal meetings, the information in the meeting request may suffice, although OOPD may ask for supplemental information via email or telephone.

B. Meeting Package

If a formal meeting is scheduled, FDA recommends that stakeholders submit a meeting package to OOPD at least 2 weeks before the meeting. Stakeholders are encouraged to submit the package electronically by email to the OOPD program contact who scheduled the meeting. In the draft guidance, FDA recommends that the meeting package contain the following information: (1) The date, time, and subject of the meeting; (2) an explanation of the meeting purposes; (3) basic information about the product to be discussed (e.g., product name or identifier, designation or application number (if applicable), proposed rare disease or condition, brief background about the product); (4) proposed meeting agenda; (5) any data, information, or presentation materials to support the discussion (if needed); and (6) a list of all individuals, with their titles and affiliations, who are expected to participate in the meeting on behalf of the stakeholder.

C. Draft Meeting Minutes

Under the draft guidance, a stakeholder should prepare a draft of summary meeting minutes for all formal meetings and certain informal meetings. These draft minutes should be sent to the OOPD program contact by email with the subject heading ''Draft Meeting Minutes.'' The draft minutes should summarize the meeting discussion points, agreements, disagreements, and action items. OOPD will review and provide any revisions to the draft meeting minutes via email, and the stakeholder will then either accept the version as final and notify OOPD to that effect or will followup with questions and/or further revisions.

Description of Respondents: Individuals from industry, researchers, patient groups, and other stakeholders who seek a meeting with OOPD regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Burden estimate: Table 1 of this document provides an estimate of the annual reporting burden for the preparation and submission of meeting

requests, meeting packages, and meeting minutes under the guidance.

Request for a meeting: Based upon information collected from OOPD program areas, approximately 2,120 informal and 46 formal meetings were requested with OOPD in fiscal year (FY) 2013 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of meeting requests and stakeholders will remain the same or will only slightly increase, and therefore estimates the total number of meeting requests will be 2,166 annually (2120 informal and 46 formal meetings). The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the information to be submitted with a meeting request in accordance with the draft guidance, is estimated to be approximately 3 hours for informal meetings and approximately 10 hours for formal meetings. Based on FDA's experience, the Agency expects that it will take stakeholders this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting. Therefore, the Agency estimates that stakeholders will spend 6,820 hours per year (6,360 hours for informal meetings and 460 hours for formal meetings) preparing meeting requests to OOPD regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Meeting package: Based upon information collected from OOPD program areas, OOPD held approximately 46 formal meetings in FY 2013 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of formal meetings, and therefore meeting packages, may increase only slightly as a result of this guidance; thus, the Agency estimates that the total responses will be 46 annually. As stated previously, it is current practice for stakeholders to submit meeting packages to the Agency in advance of any such formal meeting. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the meeting package in accordance with this draft guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to gather and copy brief statements about the product, a description of details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the Agency. Therefore, the Agency estimates that stakeholders will spend 828 hours per year submitting meeting packages to the Agency prior to a formal meeting regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Draft meeting minutes: Based upon information collected from OOPD program areas, OOPD received approximately 46 draft meeting minutes for formal meetings and 21 draft meeting minutes for informal meetings in FY 2013 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of stakeholders submitting draft meeting minutes may remain the same or increase only slightly; thus, the Agency estimates that the total number of respondents will be 67 annually. As stated previously, it is current practice for stakeholders to submit draft meeting minutes to the Agency after all formal meetings and certain informal meetings. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing draft meeting minutes in accordance with this draft guidance, is estimated to be approximately 8 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to summarize the meeting discussion points, agreements, disagreements, and action items. Therefore, the Agency estimates that stakeholders will spend 536 hours per year submitting draft meeting minutes to the Agency documenting the meeting outcomes, agreements, disagreements, and action items as followup to all formal and certain informal meetings.

FDA invites comments on this analysis of information collection burdens.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Meeting requests, packages, and minutes	Number of stakeholders	Number of responses per stakeholder	Total annual responses	Average burden per response	Total hours
Meeting Requests (informal)	2,120	1	2,120	3	6,360
Meeting Requests (formal)	46	1	46	10	460
Meeting Packages	46	1	46	18	828
Meeting Minutes	67	1	67	8	536
Total					8,184

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

III. Comments

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 necessary to send only one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or at *http://www.regulations.gov*.

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07908 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0252]

Watson Laboratories, Inc.; Withdrawal of Approval of Bupropion Hydrochloride Extended-Release Tablets, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of Bupropion Hydrochloride (HCl) Extended-Release (ER) Tablets, 300 Milligrams (mg) (Bupropion HCl ER Tablets, 300 mg), under abbreviated new drug application (ANDA) 77–715, held by Watson Laboratories, Inc. (Watson), 4955 Orange Dr., Fort Lauderdale, FL 33314. Watson has voluntarily requested that approval for this product be withdrawn and waived its opportunity for a hearing.

DATES: Effective April 9, 2014.

FOR FURTHER INFORMATION CONTACT: Carolina M. Wirth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6282, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: FDA approved ANDA 77–715 for Bupropion HCl ER Tablets, 300 mg on June 13, 2007, under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)). Bupropion HCl ER Tablets, 300 mg was indicated for the treatment of major depressive disorder. On September 24, 2013, FDA requested that Watson voluntarily withdraw its Bupropion HCl ER Tablets, 300 mg from the market after results of a bioequivalence study conducted by Watson showed that the firm's Bupropion HCl ER Tablets, 300 mg are not therapeutically equivalent to the 300-mg strength of the reference listed drug. In a letter dated September 30, 2013, Watson requested that FDA withdraw approval of the 300-mg strength of Bupropion HCl ER Tablets, approved under ANDA 77–715, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Watson also waived its opportunity for a hearing. The Agency acknowledged Watson's requests in a letter dated October 4, 2013.

Therefore, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the 300-mg strength of Bupropion HCl Extended-Release Tablets under ANDA 77–715 is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07897 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Organization, Functions, and Delegations of Authority

Part GFJ

Indian Health Service

Navajo Area Office

Part GFJ, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), as amended at 52 FR 47053–67, December 11, 1987, as amended at 60 FR 56606, November 9, 1995, as amended at 61 FR 67048, December 19, 1996, as amended at 69 FR 41825, July 12, 2004, as amended at 70 FR 24087, May 6, 2005 70 FR 60350, October 17, 2005, and most recently amended at 71 FR 69570, December 1, 2006, is hereby amended to reflect a reorganization of the Navajo Area Indian Health Service (IHS). The purpose of this re-organization proposal is to update the current approved Navajo Area IHS organization structure due to the decrease in Area shares from Federal facilities transitioning to Public Law 93–638 Indian Self-Determination and Education Assistance Act facilities. Delete the functional statements for the Navajo Area IHS in their entirety and replace with the following:

Organizations and Functions

Department of Health and Human Services
Indian Health Service (G)
Navajo Area Indian Health Service (GFJ)

Office of the Area Director (GFJ1)

(1) Plans, develops and directs the Area Program within the framework of Indian Health Service (IHS) policy in pursuit of the IHS mission; (2) delivers and ensures the delivery of high quality comprehensive health services; (3) coordinates the IHS activities and resources internally and externally with those of other governmental and nongovernmental programs; (4) promotes optimum utilization of health care services through management and delivery of services to American Indians and Alaska Natives; (5) encourages the full application of the principles of Indian preference and Equal Employment Opportunity (EEO); and (6) provides Indian Tribes and other Indian community groups with optional ways of participating in the Indian health programs including an opportunity to participate in developing the mission, values and goals for the Navajo Area Indian Health Service (NAIHS).

Branch of Planning (GFJ1A)

Provides advice on program planning and evaluation activities to include:

(1) Strategic planning coordination at the Area level, including planning, implementing, and monitoring progress on the achievement of the Area Strategic Plan; (2) facilities planning, including the development of program justification documents, program of requirements, quarters justifications, and other required facilities planning and construction documents; (3) staffing requirements and projections for Service Units, facilities projects, and other needs; (4) statistical and epidemiological reporting, analysis, and monitoring, reporting, and including monitoring health status, morbidity, mortality, patient care, health services, health systems, population, demographic, and other health related data for the Area, Service Units, Tribes, States, health programs, universities, researchers, and the general public; (5) developing and implementing data quality improvements and strategies; (6) ensuring resource allocation methodologies are current by updating and providing technical support for resource allocation to the Office of the Area Director (OAD) and the Navajo Area Management Council; (7) providing other program planning and health systems planning activities and technical support to the OAD by