safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

SAMSCA (tolvaptan) tablets, 60 mg, are the subject of NDA 22–275, held by Otsuka America Pharmaceutical, and initially approved on May 19, 2009. SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 milliequivalents/liter or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH).

Otsuka America Pharmaceutical has never marketed SAMSCA (tolvaptan) tablets, 60 mg. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Gordon Johnston Regulatory Consultants, LLC, submitted a citizen petition dated March 15, 2016 (Docket No. FDA–2016–P–0974), under 21 CFR 10.30, requesting that the Agency determine whether SAMSCA (tolvaptan) tablets, 60 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SAMSCA (tolvaptan) tablets, 60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SAMSCA (tolvaptan) tablets, 60 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SAMSCA (tolvaptan) tablets, 60 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SAMSCA (tolvaptan) tablets, 60 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to SAMSCA (tolvaptan) tablets, 60 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18139 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Food and Drug Administration

[Docket No. FDA–2016–D–1605]

Institutional Review Board Written Procedures: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS, and the Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' The purpose of this draft guidance is to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for IRBs. The draft guidance is intended for IRBs and institutions responsible for review and oversight of human subject research under the HHS or FDA regulations, or both.

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 by October 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1605 for ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5167, Silver Spring, MD 20993–0002, 301–796–4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a draft guidance document entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' This guidance is intended to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for IRBs.

OHRP and FDA frequently receive requests for clarification regarding the scope and content of IRB written procedures. We recognize that procedures may vary among institutions and IRBs due to differences in the type of research studies reviewed by the IRB, institutional policy or administrative practices, number of IRBs at the institution, affiliation with an institution, and local and State laws and regulations. In order to provide guidance on the appropriate content of written procedures, while taking into account these variations, we created an IRB Written Procedures Checklist to assist IRBs in preparing and maintaining detailed written procedures suitable for their institutions. The IRB Written Procedures Checklist incorporates the HHS and FDA regulatory requirements for IRB written procedures and additional topics that we recommend including in written procedures. The draft guidance, when finalized, will supersede OHRP's July 1, 2011, ''Guidance on Written IRB Procedures'' and FDA's 1998 ''Appendix H: A Self-Evaluation Checklist for IRBs,'' (formerly part of FDA's Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors).

To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts. OHRP and FDA believe that it will be most helpful to the regulated community to issue a joint guidance document that will clearly demonstrate the Agencies' harmonized approach to the topic of preparing and maintaining IRB written procedures.

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 OHRP's and FDA's current thinking on IRB written procedures. It does not establish any rights for any person and is not binding on OHRP, FDA, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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 referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, including the information collection activities in the provisions in 21 CFR 56.108(a)(1) and (b), have been approved under OMB control number 0910–0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115, including the information collection activities in the provisions in 45 CFR 46.103(b)(4) and (5) have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm, http://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html*, or *http://www.regulations.gov.*

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy, U.S. Food and Drug Administration.

Dated: July 15, 2016.

Karen B. DeSalvo,

Acting Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2016–18191 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the