

rule entitled, "Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use," 80 FR 29842 (donor eligibility rule) that became effective on May 23, 2016.

A small proportion of collections of blood and blood components are intended for autologous transfusion. In those instances, the autologous donor presents with a physician's prescription for the collection of the donor's blood for the donor's own upcoming medical (e.g., surgical) procedure. If the donor ultimately does not need the blood, blood establishments may, in some instances, use these donations for allogeneic (i.e. intended for transfusion to a recipient other than the donor) transfusions. This is referred to as "cross-over."

Blood establishments have requested clarification on certain requirements of the donor eligibility rule and the applicability of certain sections of the donor eligibility rule to the collection of blood and blood components intended for autologous use. To address these questions, FDA has developed this guidance to clarify the Agency's policy with respect to the requirements for autologous donors of blood and blood components intended solely for autologous use, (i.e., not subject to cross-over). Specifically, the guidance describes FDA's policy with respect to the following: The requirements in 21 CFR 630.10 related to screening autologous donors for relevant transfusion-transmitted infections; the requirement in 21 CFR 630.15(a)(1)(ii) that the responsible physician examine the autologous donor to permit more frequent collections; and, the requirement in 21 CFR 630.20(a) that the responsible physician determine and document that the autologous donor's health permits the collection of blood and blood components intended for autologous use.

Autologous donors have long been permitted to donate blood for their own use even if they do not meet certain donor eligibility criteria that apply to allogeneic donors because autologous donors are not exposed to new transfusion-transmitted infections in receiving their own blood. For example, FDA does not require testing of autologous donations for Relevant Transfusion-Transmitted Infection (RTTI) unless the donations are used for allogeneic transfusion or shipped to another establishment (21 CFR 610.40(d)). Consistent with this approach to testing autologous donations, FDA does not believe it is necessary to assess autologous donors for risks for RTTI as required in certain

provisions in § 630.10 if the donation is intended solely for autologous use.

Sections 630.15(a) and 630.20(a) describe conditions for which a responsible physician must examine and determine and document that the autologous donor's health permits a collection procedure. Autologous donors are under the care of the physician who prescribes the autologous donation. In light of the medical oversight provided by the autologous donor's physician, FDA believes blood establishments can appropriately protect autologous donors' health by following standard operating procedures that are approved by the responsible physician of the blood establishment and that define criteria for when the autologous donation may proceed and the conditions under which the responsible physician must be consulted.

The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with the donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

The guidance represents the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on 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 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 part 630 have been approved under OMB control number 0910–0795.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2016–P–0974]

### Determination That SAMSCA (Tolvaptan) Tablets, 60 Milligrams, 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 or Agency) has determined that SAMSCA (tolvaptan) tablets, 60 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for tolvaptan tablets, 60 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993–0002, 240–402–3543.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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 known generally as the "Orange Book." Under FDA regulations, drugs are 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 (§ 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.*

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## 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.