

drug products for use in the treatment of gastrointestinal diseases.

#### *D. Medical Imaging Advisory Committee*

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

#### *E. National Mammography Quality Assurance Advisory Committee*

Advises the Agency on the following: (1) Development of appropriate quality standards and regulations for mammography facilities; (2) standards and regulations for bodies accrediting mammography facilities under this program; regulations with respect to sanctions; (3) procedures for monitoring compliance with standards; (4) establishing a mechanism to investigate consumer complaints; (5) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (6) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (7) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (8) determining the costs and benefits of compliance with these requirements.

#### *F. Peripheral and Central Nervous System Advisory Committee*

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

#### *G. Vaccines and Related Biological Products Advisory Committee*

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

### **III. Criteria for Members**

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based

organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

### **IV. Selection Procedures**

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

### **V. Nomination Procedures**

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations should include a cover letter and current curriculum vitae or resume for each nominee, including a current business and/or home address, telephone number, and email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee(s) or panel(s) for

which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 27, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016-18216 Filed 8-1-16; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2016-D-2071]

#### **Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency or we) is announcing the availability of a document titled "Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry." This guidance addresses the regulatory requirements for determining donor

eligibility that apply to establishments that collect blood and blood components (blood establishments) intended solely for autologous use. On May 22, 2015, in order to better assure the safety of the nation's blood supply and to help protect donor health, FDA finalized its revision of the applicable requirements for blood establishments to test donors for infectious disease, and to determine that donors are eligible to donate and that donations are suitable for transfusion or further manufacture ("Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use" (donor eligibility rule)). The donor eligibility rule includes requirements related to current good manufacturing practice, donation testing, donor eligibility, and donation suitability. It became effective on May 23, 2016.

FDA has developed this guidance in response to questions from blood establishments concerning the applicability of the donor eligibility rule to autologous donations. The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

**DATES:** The Agency is soliciting public comment, but is implementing this guidance immediately because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

**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-2071 for "Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry." 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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled "Requirements for Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry." We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

This guidance addresses the regulatory requirements for determining donor eligibility that apply to blood establishments that collect blood and blood components intended solely for autologous use described in the final

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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**BILLING CODE 4164–01–P**

## 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