

**FEDERAL RESERVE SYSTEM****Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company**

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Federal Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than December 5, 2019.

*A. Federal Reserve Bank of San Francisco* (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. *John G. Sorensen, Jr., president of JGS, Jr. Family Holding Corporation, individually, and together with Sondra S. Swindle, president of SSS Family Holding Corporation, all of Salt Lake City, Utah;* to be approved as members of a group acting in concert to retain voting shares of Home Credit Corporation, and thereby indirectly retain voting shares of Home Savings Bank, both of Salt Lake City, Utah.

Board of Governors of the Federal Reserve System, November 18, 2019.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2019-25250 Filed 11-20-19; 8:45 am]

**BILLING CODE 6210-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier CMS-10718]

**Agency Information Collection Activities: Proposed Collection; Comment Request; Correction**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Correction of notice.

**SUMMARY:** This document corrects the information provided for [Document Identifier: CMS-10718] titled "Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form."

**FOR FURTHER INFORMATION CONTACT:** William N. Parham, III, (410) 786-4669.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the November 18, 2019, issue of the **Federal Register** (84 FR 63655), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the information collection request identified under CMS-10718, OMB control number 0938-New, and titled "Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form."

**II. Explanation of Error**

In the November 18, 2019, notice, the information provided in the first column of the first paragraph, on page 63657, was published with incorrect information in the "Total Annual Hours" section. This notice corrects the language found in the "Total Annual Hours" section in the first column of the first paragraph, on page 63657 the November 18th notice. All of the other information contained in the November 18, 2019, notice is correct. The related public comment period remains in effect and ends January 17, 2020.

**III. Correction of Error**

In FR Doc. 2019-24930 of November 18, 2019 (84 FR 63655), page 63657, the language in the first column, first paragraph of the notice that begins with "Total Annual Hours: 10,324,481" and ends with "(For policy questions regarding this collection contact Deme Umo at (410) 786-8854.)," is corrected to read as follows:

*Total Annual Hours: 7,861,354.* (For policy questions regarding this collection contact Deme Umo at (410) 786-8854.)

Dated: November 18, 2019.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2019-25283 Filed 11-20-19; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2019-D-4447]

**Transdermal and Topical Delivery Systems—Product Development and Quality Considerations; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Transdermal and Topical Delivery Systems—Product Development and Quality Considerations." This guidance provides recommendations to applicants and manufacturers of transdermal and topical delivery systems (TDS) regarding the pharmaceutical development and quality information to include in new drug applications (NDAs) and abbreviated new drug applications (ANDAs). Specifically, the guidance discusses FDA's current thinking on product design and pharmaceutical development, manufacturing process and control, and finished product control. It also addresses special considerations for areas where quality is closely tied to product performance and potential safety issues, such as adhesion failure and the impact of applied heat on drug delivery.

**DATES:** Submit either electronic or written comments on the draft guidance by February 19, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2019-D-4447 for "Transdermal and Topical Delivery Systems—Product Development and Quality Considerations." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit

both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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:

Mohamed Ghorab, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3141, Silver Spring, MD 20993, 240-402-8940.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Transdermal and Topical Delivery Systems—Product Development and Quality Considerations." Transdermal delivery systems and topical delivery systems, collectively identified as TDS, are used in a variety of therapeutic areas and treatment populations. Transdermal delivery systems are designed to deliver an active ingredient (drug substance) across the skin and into systemic circulation, while topical delivery systems are designed to deliver the active ingredient to local tissue. Both

transdermal delivery systems and topical delivery systems present similar manufacturing and quality control concerns and similar risks to patients.

The draft guidance in its entirety may not be applicable to all TDS, and some TDS (for example, microneedles, active transport TDS, reservoir TDS, and TDS applied to broken skin) have other considerations that are not addressed in this guidance. Because of the inherent failure modes and safety risks associated with the reservoir TDS, FDA recommends TDS manufacturers and applicants focus development efforts on matrix type TDS.

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 current thinking of FDA on transdermal and topical delivery systems product development and quality considerations. 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 draft 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 (PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910-0139. The collections of information in 21 CFR part 314 for the submission of NDAs and ANDAs, including the submission of labeling under 21 CFR 314.50(e)(2)(ii) and 314.50(l)(1)(i) and advertisements and promotional labeling under 21 CFR 314.81(b)(3)(i), have been approved under OMB control number 0910-0001. The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910-0572.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/>

*GuidanceComplianceRegulatory Information/Guidances/default.htm* or <https://www.regulations.gov>.

Dated: November 15, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-25246 Filed 11-20-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-4963]

#### Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on December 13, 2019, from 8 a.m. to 4 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-4963. The docket will close on December 12, 2019. Submit either electronic or written comments on this public meeting by December 12, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 12, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 12, 2019. Comments received by mail/hand delivery/courier (for

written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before December 4, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2019-N-4963 for "Dermatologic and Ophthalmic Drugs Advisory Committee;

Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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." FDA 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information 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 the 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jay R. Fajiculy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [DODAC@fda.hhs.gov](mailto:DODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the