

noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 10(c)(4)(B) of the HOLA 12 U.S.C. 1467a(c)(4)(B).

Unless otherwise noted, comments regarding the notices must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 10, 2017.

A. *Federal Reserve Bank of Dallas* (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *The SLHC Trust and The Mark and Pamela Okada Family Trust, and NexBank Capital, Inc., all of Dallas, Texas*; to continue to engage in the activities of (i) the acquisition of improved real estate to be held for rental and (ii) the maintenance and management of improved real estate pursuant to sections 238.53(b)(6) and (b)(8) of Regulation LL.

Board of Governors of the Federal Reserve System, April 19, 2017.

Margaret M. Shanks,
Deputy Secretary of the Board.

[FR Doc. 2017-08276 Filed 4-24-17; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 25, 2017.

ADDRESSES: To ensure that comments on the information collection are received, 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*. All comments should be identified with the OMB control number 0910-NEW and title "Certification of Identity for Freedom of Information Act and Privacy Act Requests." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JennaLynn Cappezuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Certification of Identity for Freedom of Information Act and Privacy Act Requests—OMB Control Number 0910-NEW

In compliance with 44 U.S.C. 3507, FDA will submit to OMB a request to review and approve a new collection of information: Certification of Identity for Freedom of Information Act and Privacy Act Requests. This new form provides the FDA with data necessary to identify an individual requesting a particular

record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is available at the following FDA FOIA page at: <https://www.fda.gov/RegulatoryInformation/FOI/default.htm>, although if an individual requests one, we will send it by mail or email. The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one's own records that are maintained in an Agency's system of records (*i.e.* the records are retrieved by that individual's name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records.

Members of the public who wish to access particular records will be asked for certain information: Name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

In the **Federal Register** of August 4, 2016 (81 FR 51455), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

As stated in table 1, the estimates are based on the following: The number of FOIA and Privacy Act requests received by FDA each year that require a certification of identity in order for FDA to process the request. Of the 10,000 requests received per year, only a small number require a certification of identity. In some cases, the requesters provide their own certification of identity. Therefore, we have estimated the number of affected individuals at 60 per year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| FDA form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 3975 | 60 | 1 | 60 | 0.17 (10 minutes) | 10 |

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

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-08303 Filed 4-24-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0008]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 25, 2017.

ADDRESSES: To ensure that comments on the information collection are received, 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 aira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0679. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act—OMB Control Number 0910-0679—Extension

FDA's guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" provides information regarding FDA's current thinking on interpreting section 914 of Title IX of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110-85). Section 914 of FDAAA added new section 505(q) to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) of the FD&C Act. The guidance describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of Agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending abbreviated new drug application (ANDA) or a 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition includes a certification and (2) supplemental information or comments to a petition include a verification. Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012 (Pub. L. 112-144). Section 1135 of FDASIA amended section 505(q) of the FD&C Act in two ways. First, it shortened FDA's deadline from 180 days to 150 days for responding to petitions subject to section 505(q) of the FD&C Act. Second, it expanded the scope of section 505(q) of the FD&C Act to include certain petitions concerning applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262), the abbreviated pathway for the approval of biosimilar biological products. Accordingly, we are now including submissions pertaining to biosimilar biological product applications in the information

collection burden estimates in this document.

Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for stay of Agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the FD&C Act requires that supplemental information or comments to such citizen petitions and petitions for stay of Agency action include a verification to be accepted for review by FDA. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) of the FD&C Act apply to a particular citizen petition or petition for stay of Agency action. The guidance states that one of the criteria for a citizen petition or petition for stay of Agency action to be subject to section 505(q) of the FD&C Act is that a related ANDA or 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of Agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act and the petitioner would like FDA to review the citizen petition or petition for stay of Agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

FDA currently has OMB approval for the collection of information entitled "General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions" (OMB control number 0910-0191). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (Commissioner) to issue, amend, or revoke a regulation or order,