

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
“Supplementary Information Certificate to Foreign Government Requests”, “Exporter’s Certification Statement Certificate to Foreign Government”, “Exporter’s Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)”.	For the export of products legally marketed in the United States.
“Supplementary Information Certificate of Exportability Requests”, “Exporter’s Certification Statement Certificate of Exportability”.	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
“Supplementary Information Certificate of a Pharmaceutical Product”, “Exporter’s Certification Statement Certificate of a Pharmaceutical Product”.	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
“Supplementary Information Non-Clinical Research Use Only Certificate”, “Exporter’s Certification Statement (Non-Clinical Research Use Only)”.	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act.

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the

FD&C Act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to the appropriate offices.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA center	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research .....	2,651	1	2,651	1	2,651
Center for Devices and Radiological Health .....	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research .....	3,680	1	3,680	1	3,680
Center for Veterinary Medicine .....	1,819	1	1,819	1	1,819
Total .....					30,500

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

Dated: November 20, 2017.  
**Leslie Kux**,  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-D-6526]

**Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled “Grandfathering Policy for Packages and

Homogenous Cases of Product Without a Product Identifier.” This draft guidance specifies whether and under what circumstances packages and homogenous cases of product not labeled with a product identifier shall be exempted, as grandfathered, from certain requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

**DATES:** Submit either electronic or written comments on the draft guidance by January 26, 2018 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 concerning the collection of information proposed in the draft guidance by January 26, 2018.

**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-2017-D-6526 for “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; Draft Guidance for Industry.” 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, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Abha Kundi, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov); or Stephen Ripley, 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 draft guidance for industry entitled “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.” On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54) was signed into law. Section 202 of the DSCSA added section 582 to the FD&C Act, which established product tracing requirements for manufacturers, repackagers, wholesale distributors, and dispensers. The DSCSA phases in its requirements over a period of 10 years.

A critical set of phased product tracing requirements outlined in section 582 of the FD&C Act (21 U.S.C. 360eee-1) relate to the product identifier. Among its provisions, section 582 requires that each package and

homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product’s standardized numerical identifier, lot number, and expiration date by specific dates. Under the statute, manufacturers must begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced into commerce no later than November 27, 2017. Repackagers are required to do the same no later than November 27, 2018.

Sections 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the FD&C Act restrict trading partners’ ability to engage in transactions involving packages and homogenous cases of product that are not labeled with a product identifier after specific dates. Beginning November 27, 2018, repackagers may not engage in a transaction involving a package or homogenous case of a product that is not encoded with a product identifier. Similar restrictions go into effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020, respectively.

Section 582(a)(5)(A) of the FD&C Act gives FDA authority to exempt packages and homogenous cases of product without a product identifier from the product tracing requirements discussed above. We are required to issue guidance that specifies whether and under what circumstances we will exercise this authority. The draft guidance addresses this requirement. As explained in the draft guidance, only packages and homogenous cases of product that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 are eligible for an exemption under section 582(a)(5)(A).

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 Agency’s current thinking on the grandfathering policy for packages and homogenous cases of product without a product identifier. Guidance documents generally do 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. For this particular document, section 582 of the FD&C Act gives FDA authority to issue binding guidance specifying the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier shall be exempted from the requirements of section 582 of the FD&C Act. Thus, insofar as section IV of this

guidance specifies the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 of the FD&C Act shall be exempted from certain requirements of section 582, it will have binding effect upon finalization.

**II. Electronic Access**

Persons with access to the internet may obtain the guidance document at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: November 20, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0076]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Signatures**

**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 December 27, 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](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0303. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7729, [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov).

**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.

**Electronic Records; Electronic Signatures**

*OMB Control Number 0910-0303—Extension*

This information collection supports FDA regulations; specifically, in part 11 (21 CFR part 11), which sets forth criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using

electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records. The respondents are businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

In the **Federal Register** of June 19, 2017 (82 FR 27838), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the information collection topics solicited in the notice. However, one comment was received regarding a related Agency draft guidance entitled, “Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR part 11—Questions and Answers,” and the comment has been directed to the appropriate Agency components for consideration.

We therefore estimate the burden of this collection of information as follows:

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>**

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
11.100 .....	4,500	1	4,500	1	4,500

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