TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Abbreviated New Animal Drug Applications	0910–0669	10/31/2022
Medical Devices: Use of Certain Symbols in Labeling—Glossary to Support the Use of Symbols in Labeling	0910–0740	10/31/2022
Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act	0910–0768	10/31/2022
Investigational Device Exemptions Reports and Records	0910–0078	11/30/2022
510(k) Third-Party Review Program	0910–0375	11/30/2022
Guidance for Industry With the Center for Veterinary Medicine's Electronic Submission System	0910–0454	11/30/2022

Dated: December 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28249 Filed 12–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 January 30, 2020.

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 0910–0720. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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.

Unique Device Identification System—21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830

OMB Control Number 0910–0720—Extension

In accordance with the Unique Device Identification (UDI) system (see 21 CFR part 801, subpart B), medical device labelers, unless excepted, are required to design and use medical device labels and device packages that bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes.

The recordkeeping, reporting, and third-party disclosure requirements referenced in this document are imposed on any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but other types of labelers include a specification developer, a single-use device reprocessor, a convenience kit assembler, a private label distributor, a repackager, or a relabeler. Respondents may also include any private organization that applies for accreditation by FDA as an issuing agency.

FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the table that follows:

Section 801.18 requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Section 801.20 requires every medical device label and package to bear a UDI.

Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the label of that device and utilize the GUDID.

Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use.

Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software.

Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, under § 830.60 it has to keep a record showing the relationship of the original device identifier to the new device identifier.

Section 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing to furnish FDA an application containing certain information, materials, and supporting documentation.

Under § 830.120, an FDA-accredited issuing is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs.

Sections 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waiver.

Section 830.360 requires each labeler to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

Respondents who are required to submit data to the Agency under certain other approved information collections (listed below) are required to include UDI data elements for the device that is the subject of such information collection. Addition of the UDI data elements is included in this burden estimate for the conforming amendments in the following 21 CFR parts:

Part 803—Medical Device Reporting (OMB control number 0910–0437),

Part 806—Medical Devices; Reports of Corrections and Removals (OMB control number 0910–0359),

Part 814—Premarket Approval of Medical Devices (OMB control number 0910–0231),

Part 820—Quality System Regulation (OMB control number 0910–0073),

Part 821—Medical Device Tracking Requirements (OMB control number 0910–0442), and

Part 822—Postmarket Surveillance (OMB control number 0910–0449).

In the **Federal Register** of July 31, 2019 (84 FR 37315), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics.

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

TABLE 1—ESTIMATED ANNUAL BURDEN

	Number of respondents [1]	Number of responses per respondent [2]	Total annual responses [3]	Average burden per response [4]	Total hours [5]	Total capital costs and operating and maintenance costs
Reporting	6,199	51	316,149	0.023 (1 minute)	7,289	$425,000
Recordkeeping	5,987	51	305,337	0.989 (59 minutes)	302,121	14,733,333
Third-Party Disclosure	5,987	51	305,337	0.885 (53 minutes)	270,143	13,033,333

[1] Maximum number of respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

[2] Maximum number of responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

[3] Maximum total annual responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

[4] Rounded to three decimals. Total hours reflects a more precise, non-rounded average burden per response. An approximate (non-rounded) conversion to minutes is shown in parentheses.

[5] Total hours is based on a more precise burden per response than the rounded value show in this table.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28246 Filed 12–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3586]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 (PRA).

DATES: Fax written comments on the collection of information by January 30, 2020.

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 0910–0677. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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.

Focus Groups About Drug Products as Used by the Food and Drug Administration

OMB Control Number 0910–0677—Extension

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have three major purposes:

- To obtain information that is useful for developing variables and measures for quantitative studies;
- to better understand people's attitudes and emotions in response to topics and concepts; and
- to further explore findings obtained from quantitative studies.

We use information gathered from focus group findings to test and refine ideas and to help develop messages and other communications, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

Our Center for Drug Evaluation and Research, as well as other Agency components, engage focus groups about