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

regulated drug products on a variety of topics related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials. These materials may include, but are not limited to direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sales of medical products, and consumer and professional education.

In the **Federal Register** of July 17, 2019 (84 FR 34186), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Annually, we project that 20 studies will be initiated using 160 focus groups with an average of 9 persons per group. We assume each focus group will last an average of 1.75 hours.

We estimate the burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Group Study	1,440	1	1,440	1.75	2,520

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

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 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28247 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–2019–N–5955]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; AB-FUBINACA; 5F-AMB-PINACA; 5F-MDMB-PICA; 4-F-MDMB-BINACA; 4-CMC; N-ethylhexedrone; alpha-PHP; DOC; Crotonyl Fentanyl; Valeryl Fentanyl; Flualprazolam and Etizolam; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States' position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in March 2020. This notice is issued under the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments by January 30, 2020. The short time period for the submission of comments is needed to ensure that Health and Human Services (HHS) may, in a timely fashion, carry out the required action and be responsive to the United Nations.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 30, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 30, 2020. 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.

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-5955 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; AB-FUBINACA; 5F-AMB-PINACA; 5F-MDMB-PICA; 4-F-MDMB-BINACA; 4-CMC; N-ethylhexedrone; alpha-PHP; DOC; Crotonyl Fentanyl; Valeryl Fentanyl; Flualprazolam and Etizolam; 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