1. Placement Authorization (Form P–1)
2. Authorization for Medical, Dental, and Mental Health Care (Form P–2)
3. Intakes Placement Checklist
4. Transfer Request (Form P–10A)
5. Transfer Summary and Tracking (formerly titled Transfer Request and Tracking Form) (Form P–11)
6. UC Portal Capacity Report (Form P–12)
7. Add New UC (Form P–13)
8. ORR Transfer Notification—Notice of Transfer to Immigration and Customs Enforcement's (ICE) Chief Counsel—Change of Address/ Change of Venue (Form P–14)

Respondents: ORR grantee and contractor staff, other federal agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden *minutes* per response	Annual total burden *hours*
Placement Authorization (Form P–1)	216	278	5	5,004
Authorization for Medical, Dental, and Mental Health Care (Form P–2)	216	278	5	5,004
Notice of Placement in a Restrictive Setting (Form P–4/4s)	15	34	20	170
Long Term Foster Care Placement Memo (Form P–5)	30	3	15	23
UC Referral (Form P–7)	16	3,250	60	52,000
UC Referral—Intakes Placement Checklist (Form P–7)	16	9	30	72
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	216	10	15	540
Medical Checklist for Transfers (Form P–9A)	216	27	5	486
Medical Checklist for Influx Transfers (Form P–9B)	216	63	10	2,268
Transfer Request (Form P–10A)—Grantee Case Manager	216	37	25	3,330
Transfer Request (Form P–10A)—Contractor Case Coordinator	250	37	20	3,083
Influx Transfer Request (Form P–10B)	216	63	25	5,670
Transfer Summary and Tracking (Form P–11)	216	37	10	1,332
Program Entity (Form P–12)	216	12	30	1,296
UC Profile (Form P–13)	216	241	45	39,042
ORR Transfer Notification—ORR Notification to ICE Chief Counsel of Transfer of UC and Request to Change Address/Venue (Form P–14)	216	37	10	1,332
Family Group Entity (Form P–15)	16	188	5	251
Influx Transfer Manifest (Form P–16)	3	12	20	12
Influx Transfer Manual and Prescreen Criteria Review (Form P–17)	216	43,333	30	4,679,964
Estimated Annual Burden Hours Total	.....	.....	.....	4,800,879

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement,* No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–21999 Filed 10–7–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1262]

Surgical Staplers and Staples for Internal Use—Labeling Recommendations; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a final guidance entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' FDA is issuing this guidance to provide labeling recommendations for surgical staplers and staples for internal use. These labeling recommendations are being issued because malfunctions and misuse associated with these devices have resulted in serious adverse events, including deaths.

DATES: The announcement of the guidance is published in the **Federal Register** on October 8, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–1262 for ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: George Gibeily, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4660, Silver Spring, MD 20993–0002, 301–796–0276.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' Surgical staplers for internal use are specialized prescription devices used to deliver compatible staples to internal tissues during surgery for resection, transection, and creating anastomoses. Surgical staplers and staples for internal use may be indicated for use in a wide range of surgical applications, including but not limited to gastrointestinal, gynecologic, and thoracic surgery. FDA developed this guidance because we had become aware of a large number of adverse events associated with use of both surgical staplers and staples for internal use. Both device misuse and device malfunctions are root causes of these adverse events. FDA believes that these problems may be mitigated by providing specific information about the risks, limitations, and directions for use in the labeling for the surgical staplers and staples for internal use.

This guidance is intended to provide recommendations for information that should be included in the product labeling for surgical staplers and staples for internal use, including contraindications, warnings, directions for use, and technical characteristics and performance parameters. Elsewhere in this issue of the **Federal Register**, FDA is announcing the final reclassification of surgical staplers for internal use from class I to class II with special controls. Some of the labeling recommendations in this guidance are intended to provide additional recommendations in order to help manufacturers comply with the labeling requirements as part of the special controls for surgical staplers for internal use.

A notice of availability of the draft guidance appeared in the **Federal Register** of April 24, 2019 (84 FR 17174). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revisions to the contraindications and warnings to avoid being overly prescriptive and not interfere with physicians' decision making under practice of medicine where appropriate. Revisions were also made to refine the directions for use and technical characteristics recommendations in response to feedback, as also described in the final reclassification of surgical staplers for internal use announced elsewhere in this issue of the **Federal Register**. FDA also added the relevant special controls language in order to make it clear what are requirements under the special controls and what are further clarifying recommendations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18013 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: October 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22042 Filed 10–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1048]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

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: Submit written comments (including recommendations) on the collection of information by November 8, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0485. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Medical Device Labeling Regulations

OMB Control No. 0910–0485—Revision

This information collection supports implementation of medical device labeling requirements governed by section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), codified in Agency regulations, and discussed in associated Agency guidance. Medical device labeling requirements, among other things, provide for the label or labeling content of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions under section 502 of the FD&C Act require that manufacturers, importers, and distributors of medical devices disclose information about themselves or the devices on the labels or labeling for the devices. Section 502 provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use. Medical device labeling regulations in parts 800, 801, 809, and associated regulations in parts 660 and 1040 (21 CFR parts 660, 800, 801, 809, and 1040), prescribe the disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves and/or the devices, on the label or labeling for the devices, to health professionals and consumers.

In conjunction with provisions in part 800, part 801, subpart A sets forth general labeling provisions applicable to all medical devices, including content and format requirements pertaining to intended uses, adequate directions for use, misleading statements, and the prominence of required labeling. Provisions found in part 801, subpart B pertaining to labeling requirements for Unique Device Identification are currently approved under OMB control number 0910–0720 and not covered in this information collection request. Information collection associated with labeling requirements for Over-the-Counter (OTC) Devices are found in part 801, subpart C, and cover principal display panel; statement of identity; declaration of net quantity of contents; and certain warning statement elements. Information collection associated with exemptions from adequate directions for use and other exemptions are found in part 801, subparts D and E, respectively. Information collection associated with special labeling requirements applicable to specific devices are found in part 801, subpart H. We also include information collection associated with labeling for in vitro diagnostic products for human use, as set forth in part 809, subpart B. In addition to the labeling requirements in part 801 and the certification and identification requirements of 21 CFR 1010.2 and 1010.3, sunlamp products and ultraviolet lamps are subject to specific labeling requirements as set forth in part 1040.

The information collection also includes provisions associated with stand-alone symbols (not accompanied by explanatory text adjacent to the symbol), when accompanied by a symbols glossary, as set forth in part 660, additional standards for diagnostic substances for laboratory standards for biological products, subparts A, C, D, E, and F. The requirements are also found in the general medical device labeling regulations part 801, subpart A, and part 809, subpart B.

The information collection also helps to implement section 502(b) of the FD&C Act which requires that, for packaged devices, labeling must bear the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires also that the labeling for a device must contain adequate directions for use unless FDA grants an exemption. Section 502(u) requires reprocessed single-use devices (SUDs) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Under this provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by