to develop and support FDA's policies related to tobacco products, including their labels, labeling, and advertising. Data will be collected from the panel primarily through the use of randomized experimental designs, however, there may be data collected through the use of other methods, such as surveys, interviews, or online group discussions. Given the limitations on the existing Web-based panels, it is important to develop a new panel of tobacco users that balances the need to conduct experiments while limiting the number of tobacco-related studies per year so as to not bias study results.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity or type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Household Screening Respondent	29,385	0.33	9,697	0.16 (10 minutes)	1,552
Panel Member Enrollment Survey	4,000	0.33	1,320	0.25 (15 minutes)	330
Panel Member Baseline Survey		0.33	1,320	0.25 (15 minutes)	330
Panel Maintenance/Bi-annual Update Surveys		3.0	12,000	0.08 (5 minutes)	960
Experimental/Observational Studies *		2.7	10,800	0.33 (20 minutes)	3,564
Panel Replenishment Screening Respondent	10,285	0.50	5,143	0.16 (10 minutes)	823
Panel Replenishment Enrollment Survey **	2,800	0.33	924	0.25 (15 minutes)	231
Panel Replenishment Baseline Survey **	2,800	0.33	924	0.25 (15 minutes)	231
Cognitive Interview Subjects	20	0.33	7	1.0	7
Focus Group Subjects	20	0.33	7	1.5	10
Total	49,310				8,038

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

* Includes a total of 8 experimental or observational studies over a 3-year period for each of the 4,000 panel members who are active at the time of each study. The first study (Study 1) is included in this clearance request; the remaining studies will be funded under separate task orders but are included in this table to present an overall estimate of the burden for each participating panel member.

** Assumes 1,400 additional panel members will be recruited annually (2,800 total) as part of the panel replenishment effort.

The burden above was estimated using data from timed-readings of each instrument, including the mail and field screeners, enrollment survey, baseline survey, panel maintenance questionnaires, and Study 1 questionnaire.

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24538 Filed 10–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0555]

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

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 November 17, 2014.

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 0910–0442. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Devices; Device Tracking—21 CFR part 821 (OMB Control Number 0910–0442)—Extension

Section 211 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(e)(1) and (e)(2)) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''), or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and

patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1 to 3 of this document are based on the number of device tracking orders issued in the last 3 years.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget under the PRA (44 U.S.C. 3501–3520). The collections of information found in §§ 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910–0183.

In the **Federal Register** of April 25, 2014 (79 FR 22991), 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 solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	1	1	1	1	1
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					4

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	12	1	12	76	912
Record of tracking data—821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) [2]	12	1	12	63	756
Manufacturer data audit—821.25(c)(3)	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

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

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24599 Filed 10–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1675]

New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products.'' This guidance sets forth a change in the Agency's interpretation of the 5-year new chemical entity (NCE) exclusivity statutory and regulatory provisions as they apply to certain fixed-combination drug products (fixed combinations). As described in the guidance, a drug product will be eligible for 5-year NCE exclusivity if it contains a drug substance that meets the definition of ''new chemical entity,'' regardless of whether that drug substance is approved in a single-ingredient drug product or in certain fixed-combinations. This guidance finalizes the draft guidance issued in February 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, 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 guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455; or Jay Sitlani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 301–796–5202.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products.'' This guidance sets forth a change in the Agency's interpretation of the 5-year NCE exclusivity provisions as they apply to certain fixed-combinations. Section 505(c)(3)(E)(ii) and (j)(5)(F)(ii) of the Food, Drug, and Cosmetic Act and 21 CFR 314.108, among other provisions, establish the scheme under which a drug product is eligible for 5-year NCE exclusivity. The Agency historically interpreted the term ''drug'' as it appears in the first sub-clause of the statutory provisions and in the definition of ''new chemical entity'' in its regulation to mean ''drug product.'' This resulted in a fixed-combination not being eligible for 5-year NCE exclusivity if it contained any drug substance that contained an active moiety that had been previously approved by the Agency, even if the fixed-combination also contained another drug substance that contained a previously unapproved active moiety.

The Agency recognizes, however, that fixed-combinations have become increasingly prevalent in certain therapeutic areas and that these products play an important role in optimizing adherence to dosing regimens and improving patient outcomes. Therefore, to further incentivize the development of fixed-combinations containing previously unapproved active moieties, the guidance sets forth the Agency's revised interpretation regarding the eligibility for 5-year NCE exclusivity of certain fixed-combinations. Under the revised interpretation, the term ''drug'' in the relevant provisions is interpreted to mean ''drug substance'' or ''active ingredient,'' and not ''drug product.'' Accordingly, a drug product is eligible for 5-year NCE exclusivity provided that it contains a drug substance that contains no active moiety that has been previously approved. This will permit a drug substance that meets the definition of new chemical entity (i.e., one that contains no previously approved active moiety) to be eligible for 5-year NCE exclusivity, regardless of whether it is approved in a single-ingredient drug product, in a fixed-combination with another drug substance that contains no other previously approved active moiety, or in a fixed-combination with another drug substance that contains a previously approved active moiety.

In the **Federal Register** of February 24, 2014 (79 FR 10167), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance. We have made editorial changes primarily for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on 5-year NCE exclusivity for certain fixed-combinations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR parts 314 have been approved under OMB control number 0910–0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*