312.32, 312.38, 312.55, and 312.56 have been approved under OMB control number 0910–0014; 21 CFR 314.50 has been approved under OMB control number 0910–0001; and 21 CFR 812.35 and 812.150 have been approved under OMB control number 0910–0078.

In the **Federal Register** of May 31, 2018 (83 FR 25015), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of guidance/reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
5. Sponsor reporting to FDA on DMC recommendations related to safety.	37	1	37	0.50 (30 minutes) ..	18.5

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Section of guidance/recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual responses	Average burden per recordkeeping	Total hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

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

Section of guidance/disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.4.1.2. Sponsor notification to the DMC regarding waivers.	1	1	1	0.25 (15 minutes) ...	0.25
4.4.3.2. DMC reports of meeting minutes to the sponsor.	370	2	740	1	740
Total					740.25

[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: September 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19799 Filed 9–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1960]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

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 October 12, 2018.

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 0910–0291 and title ''MedWatch: The Food and Drug Administration Medical Products Reporting Program.'' 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, 301–796–5733, *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.

MedWatch: The FDA Medical Products Reporting Program

OMB Control Number 0910–0291—Revision

This information collection supports FDA's MedWatch safety information and adverse event reporting program. Members of the public use FDA's MedWatch system to report adverse events, product problems, errors with the use of a human medical product, or when evidence of therapeutic failure is suspected or identified in clinical use.

To ensure the marketing of safe and effective products, it is critical that postmarketing adverse outcomes and product problems are reported for all FDA-regulated human healthcare products, including drugs (prescription and nonprescription), biologics, medical devices, dietary supplements, and other special nutritional products (*e.g.* infant formula and medical foods), and cosmetics. To facilitate reporting on human medical products (except vaccines) during their postapproval and marketed lifetimes, we have developed three forms (collectively known as the MedWatch forms). Form FDA 3500 is intended to be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals; Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation); and Form FDA 3500B is written in plain language and is intended to be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Information collected by the forms is used to assess and evaluate risks associated with FDA-regulated products, enabling us to take appropriate action to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

I. Background

A. Authorizing Statutes and Codified Regulations

The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b, 355, 360i, 360*l,* and 393) and the Public Health Service Act (42 U.S.C. 262) require FDA to collect mandatory adverse event reports from regulated industry on medical products once they have been approved for marketing, enabling the Agency to monitor the safety of drugs, biologics, medical devices, and dietary supplements. Postmarket reporting for medical foods, infant formula, cosmetics, and tobacco products is done voluntarily.

Requirements regarding mandatory reporting of adverse events or product problems are codified at parts 310, 314, 600, and 803 (21 CFR parts 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and specified in sections 503B, 760, and 761 of the FD&C Act (21 U.S.C. 353b, 379aa, and 379aa–1). Mandatory reporting of adverse reactions for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) is codified at § 1271.350 (21 CFR 1271.350).

B. Voluntary Reporting: Form FDA 3500

Voluntary reporting of adverse events is completed using Form FDA 3500 and may be used by healthcare professionals to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the Agency or the manufacturer with the exception of Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1). Reports for vaccines are not submitted via MedWatch or MedWatch forms, but are submitted to the Vaccines Adverse Event Reporting System, which is jointly administered by FDA and the Centers for Disease Control and Prevention and approved under OMB control number 0910–0308.

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries. Under Federal law and regulation, section 761(b)(1) of the FD&C Act, a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act (21 U.S.C. 342) after that product is marketed. Therefore, the Agency depends on the voluntary reporting by health professionals, and especially by consumers, of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were previously received by the Agency on paper versions of Form FDA 3500 (or Form FDA 3500B) (by mail or Fax). Currently, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal (*https://www.safetyreporting.hhs.gov/* approved under OMB control number 0910–0645). In that case, Form FDA 3500 (or Form FDA 3500B) is not used.

Form FDA 3500 may be used to report to the Agency serious adverse events, product problems, and product use errors and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or Fax paper forms to the Agency (a fillable PDF version of the form is available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf*) or reporters may electronically submit a report via the MedWatch Online Voluntary Reporting Form (*https://www.accessdata.fda.gov/scripts/medwatch/*). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription (over-the-counter (OTC)) human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements. Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal (*https://www.safetyreporting.hhs.gov/*).

C. Mandatory Reporting: Form FDA 3500A

1. Drug and Biological Products

In sections 505(b) and (j), 503B, and 704 (21 U.S.C. 355(b) and (j), 353B, and 374) of the FD&C Act, Congress has required that important safety information relating to all human drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biological products). Mandatory reporting of adverse reactions for HCT/Ps has been codified in § 1271.350.

2. OTC Monograph Drug Products and Dietary Supplements

Section 760 of the FD&C Act provides for mandatory safety reporting for non-prescription human drug products marketed without an approved application as described in the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462), which became law on December 22, 2006. The law requires manufacturers, packers, and distributors of nonprescription, OTC human drug products marketed without an approved application (OTC monograph drug products) to submit reports of adverse experiences from domestic sources. The law also requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements.

3. Postmarketing Safety Reports—Changes in Format Starting in June 2018

Current requirements specify that postmarketing adverse experience reports must be submitted on paper on Form FDA 3500A (or the CIOMS) (Council for International Organizations of Medical Sciences) I form for serious, unexpected adverse experiences from a foreign source). For the last several years the Agency has accepted electronic submissions in lieu of the paper Form FDA 3500A on the condition they are submitted in a manner that the Agency can process, review, and archive. On June 10, 2014, the Agency issued a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements'' (79 FR 33072) that requires electronic submission of all mandatory postmarketing safety reports, including individual case safety reports. Entities with mandatory reporting obligations under parts 310 and 314 (drugs) and 600 (biological products) and specified under section 760 of the FD&C Act must implement this rule within 1 year of the issuance date (by June 10, 2015). For more information see: *https://www.gpo.gov/fdsys/pkg/FR-2014-06-10/pdf/2014-13480.pdf*.

4. Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information, as the Secretary of Health and Human Services may, by regulation, reasonably be required to provide assurance that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Devices Act of 1990 (Pub. L. 101–629), signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of Form FDA 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), signed into law October 26, 2002, amended section 519 of the FD&C Act. The MDUFMA amendment (section 303) required FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

D. Voluntary Reporting by Consumers: Form FDA 3500B

Form FDA 3500B was developed for voluntary reporting by consumers (*i.e.* patients and their caregivers) to submit reports not mandated by Federal law or regulation. Individual patients or their caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer.

FDA supports and encourages direct reporting to the Agency by consumers and healthcare professionals of suspected serious adverse outcomes and other product problems associated with human medical products, (*https://www.fda.gov/Safety/ReportaProblem/default.htm*). FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

On March 25, 2008, section 906 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) amended section 502(n) of the FD&C Act (21 U.S.C. 352(n)) and mandated that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *https://www.fda.gov/safety/medwatch,* or call 1–800–FDA–1088.''

Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit reporting via the MedWatch process. For this reporting FDA has created Form FDA 3500B, a modified version of Form FDA 3500 tailored for consumers and written in plain language (in conformance with the Plain Writing Act of 2010 (Pub. L. 111–274), *https://www.gpo.gov/fdsys/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*).

Form FDA 3500B evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies, and with extensive input from consumer advocacy groups and the general public. Form FDA 3500B may be used to report to the Agency adverse events, product problems, and product use errors. The form is provided in both paper and electronic formats. Reporters may mail or Fax paper forms to the Agency (a fillable PDF version of the form is available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf*) or electronically submit a report via the MedWatch Online Voluntary Reporting Form (*https://www.accessdata.fda.gov/scripts/medwatch/,* approved under OMB control number 0910–0645). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription OTC human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements. Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal (*https://www.safetyreporting.hhs.gov/,* approved under OMB control number 0910–0645).

II. Proposed Modification to Existing Forms FDA 3500, 3500A, and 3500B

A. General Changes

The proposed modifications to Form FDA 3500 and Form FDA 3500A reflect changes that will bring the form into conformity, since the previous OMB authorization in 2015, with current regulations, rules, and guidances and fall into three categories: (1) Regulatory driven revisions, (2) work improvements for the Center, and (3) report processing improvements. We also welcome comments about translation of Form FDA 3500B (consumer) into Spanish and other languages. Lastly, formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information.

B. Changes Proposed for Form FDA 3500

In section A, we are revising the heading of A3 to ''Current Gender'' followed by check boxes next to the following options ''Female'', ''Male'', ''Intersex'', ''Transgender'', ''Prefer not to disclose.''

In section B, we are revising B1 to ''Type of Report (check all that apply)''. In section B2, we are removing ''(Devices)'' from the last option. We are also splitting section B6 into two

questions: ''B6.a. Relevant Test (please included dates)'' and ''B6.b. Relevant Laboratory Data (please included dates).''

In section C, we are adding question C2 ''Do you have a picture of the product?''

In section D1, we are adding the question ''Does this report involve cosmetics, dietary supplements or food?'' followed by a checkbox for ''Yes.'' In section D4, we are adding the question ''Is therapy still on-going?'' This question is important for pharmacovigilance and the current form does not allow the reporter to be specific. The current form does not allow the reporter to be specific. It is proposed to combine boxes D6 and D7 and change the title to ''Product Type'' (check all that apply).

In section E, we are adding question E9 ''Was this device serviced by a third-party servicer?'' followed by a checkbox for ''Yes'' and a checkbox for ''No.''

C. Changes Proposed for Form FDA 3500A

In section A, we are revising the heading of A3 to ''Current Gender'' followed by check boxes next to the options ''Female'', ''Male'', ''Intersex'', ''Transgender'', ''Prefer not to disclose''.

In section B, we are revising the heading for BI to now read ''Type of Report (check all that apply)''. In section B2, we are removing ''(Devices)'' from the last option. Section B6 is being split into two questions: ''B6.a. Relevant Test (please include dates)'' and ''B6.b. Relevant Laboratory Data (please include dates),''

In section C, we are combining boxes C6 and C7 and changing the title to ''Product Type'' (check all that apply).

In section D, we are adding a new question ''Was this device serviced by a third party?'' followed by a checkbox for ''Yes'' and a checkbox for ''No.''

In section F, we are changing the revising the heading of F10 to ''Adverse Event Problem'' and splitting the ''Patient Code'' box into two fields entitled ''Patient Outcome Code'' and ''Patient Severity Code.'' We are also splitting the ''Device Code'' field into two fields entitled ''Device Code'' and ''Component Code.''

In section G, question G1 will now include ''or Compounding Outsourcing Facility'' after (and Manufacturing Site for Devices.)'' In section G5, we are adding two new options entitled ''PreANDA'' and ''Compounded Product'' followed by a check box for ''Yes,'' and making consistent changes within section G6 by replacing ''If IND,'' to ''Give Protocol #.''

In section H1, we are adding a check box to indicate whether a summary report is included followed by a field in which to indicate ''Number of Events Summarized'' and an open field in which to add text. We are renaming section H6 to ''Adverse Event Problem'' and splitting ''Patient Code'' into two fields entitled ''Patient Outcome Code'' and ''Patient Severity Code.'' We are also splitting ''Device Code'' into two fields entitled ''Device Code'' and ''Component Code.'' In section H6, we are renaming the headings as follows: (1) ''Method'' to ''Type of Investigation'' (2) ''Results'' to ''Investigation Findings'' and (3) ''Conclusions'' to ''Investigation Conclusion.'' Finally, H10 is becoming a field entitled ''Additional Manufacturer Narrative,'' and we are adding field H11 entitled ''Corrected Data.''

D. Changes Proposed for Form FDA 3500B

On page 1, we are removing the text ''nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods.'' We are also going to number each of the questions included.

In section A, for the question ''Did any of the following happen?'' we are removing ''Devices)'' from the last option. We are also revising the question ''List any relevant tests or laboratory data if you know them. (Include dates)'' as two separate questions: ''List any relevant tests (Include dates)''; and ''List any relevant laboratory data (Include dates)'' with corresponding date fields for ''relevant tests'' and ''laboratory data.''

In section B, we are asking whether respondents have a picture of the product. Also in section B, we are adding the questions ''Does this report involve cosmetics, dietary supplements, or food?'' and ''Is therapy still on-going?'' These questions pertain to pharmacovigilance and the current form does not allow for such specificity. We are also adding the question, ''Was the product compounded by a pharmacy or an outsourcing facility?'' Following the question, ''Is the Product Compounded?'' we are adding a check box for ''Yes'' and a checkbox for ''No.'' We are also adding checkboxes within the field ''Product Type (check all that apply)'' to correspond with selections for ''Over-the-Counter, Generic and Biosimilar.'' Finally, we are revising ''Name of the . . .'' to ''Name(s) of the . . .'' for clarity.

In section C, we are separating ''Other identifying information'' into two fields; hoping this improves reporting. New fields will be entitled (1) ''Model number'' (2) ''Catalog number'' (3) ''Lot number'' (4) Serial number'' (5) ''UDI Number and (6) ''Expiration Date.''

In section D we are changing the terminology from ''Sex'' to ''Current Gender'' followed by corresponding check boxes next to the options ''Female'', ''Male'', ''Intersex'', ''Transgender'', ''Prefer not to disclose''.

In section E, we are revising the question ''If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box:'' to read ''If you do NOT want your identity disclosed to the manufacturer/compounder, place an 'X' in this box:''

III. Public Comment

In the **Federal Register** of March 16, 2018 (83 FR 11756), we published a 60-day notice requesting public comment on the proposed collection of information. A number of comments were received and are discussed in the following paragraphs.

General comments included suggestions that the MedWatch program be better advertised to physicians and other medical healthcare professionals as well as patients. Also, that the forms use terminology more familiar to healthcare providers and consumers. For example, using 'Medication error' or 'Medication error/product use error' instead of 'Product use error' to ensure respondents are aware that MedWatch forms can be used to report medication errors. Other comments suggested revisions that might improve or otherwise clarify instructions. Finally, some comments pertained to the advantages of electronic reporting.

More specific comments included a suggestion to add a question to section A of Form FDA 3500 related to pregnancy. While we agree that documenting pregnancy status is important, we do not plan on adding an additional checkbox for pregnancy at this time. Previously (in 2005), we proposed adding checkboxes for both ''Product Used During Pregnancy'' and ''Product Used During Breast Feeding.'' However we received comments expressing concern that these new data fields introduced divergence from International Council on Harmonisation standards and appeared to duplicate information usually provided in the narrative section and in coded adverse event terms. At the same time, we ask readers to note that pregnancy status can be captured in field B7 under ''other relevant history.''

Another comment suggested adding ''Physician Assistant'' to the drop down ''Occupation'' menu in section G of Form FDA 3500. We appreciate this

suggestion and will implement the revision.

We also received comment that some users have experienced ''timing out'' while completing Form FDA 3500B online and requested that any time limit for completing online forms be extended. We were not aware of this issue and will investigate to see whether it relates to the online functionality of the form. If so, we will make the necessary adjustments.

While we are especially appreciative of the comments received in response to our notice, we continue to welcome feedback at all times regarding ways we might improve the MedWatch Program and the associated forms. In addition to the revisions discussed previously, on our own initiative we are now including burden associated with written submissions under § 329.100(c)(2) (21 CFR 329.100(c)(2)) that request a temporary waiver from the electronic reporting requirements associated with postmarket adverse drug events under section 760 of the FD&C Act. While we expect few such waiver requests, we retain a placeholder for one respondent annually, and we estimate it takes 1 hour to complete the request.

We therefore estimate the burden for the information collection as follows.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center or 21 CFR section and/or FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form 3500	14,727	1	14,727	0.66 (40 minutes)	9,720
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80, and 1271.350).	599	98	58,702	1.21	71,029
Form 3500A (§ 310.305 outsourcing facilities)	50	2	100	1.21	121
Center for Devices and Radiological Health:					
Form 3500	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (part 803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition:					
Form 3500	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products:					
Form 3500	39	1	39	0.66 (40 minutes)	26
All Centers:					
Form 3500B	13,750	1	13, 750	0.46 (28 minutes)	6,325
Written requests for temporary waiver under § 329.100(c)(2):	1	1	1	1	1
Total					909,396

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

While we retain the currently approved estimate for the information collection, as noted previously we have added burden associated with written submissions under § 329.100.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19742 Filed 9–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3010]

Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient.'' This public workshop is intended to discuss potential candidate biomarkers to determine organ transplant patients' immunologic risk for organ rejection or tolerance. The public workshop will include discussion of the biomarker qualification process and how it could be used to develop biomarkers for use in clinical trials in transplantation, to develop new drugs to address unmet needs, and in clinical practice to guide patient treatment selection. Speakers will be patients who will provide perspective on the challenges of living with a transplant, managing immunosuppression and perspectives on tolerability, adherence, and risk that may inform patient-reported outcome (PRO) and patient-focused drug development.

DATES: The public workshop will be held on September 27, 2018, from 8:30 a.m. to 6 p.m. and September 28, 2018, from 8 a.m. to 12:30 p.m. Submit either electronic or written comments on this public workshop by November 19, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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 November 19, 2018. The