FDA is revising the first paragraph of the agenda for that meeting to read as follows:

On Thursday, March 22, 2018, the PAC and EMDAC will meet to discuss drug development for the treatment of children with achondroplasia (ACH). The following topics should be considered for discussion: Evidence required to establish dose-response, study design, study duration, intended population, and endpoints. In the open session, the committee does not intend to discuss any individual research programs.

FDA is also changing the meeting procedure and closed committee deliberations as follows:

Procedure: On March 22, 2018, from 12 p.m. to 6 p.m., the meeting is open to the public.

Closed Committee Deliberations: On March 22, 2018, from 8 a.m. to 11 a.m., the meeting will be closed to permit committee review and discussion of trade secret and/or confidential commercial information.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05413 Filed 3–15–18; 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; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on revisions to Forms FDA 3500, 3500A, and 3500B used in the FDA Medical Products Reporting Program.

DATES: Submit either electronic or written comments on the collection of information by May 15, 2018.

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 May 15, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 15, 2018. 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–2014–N–1960 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The FDA Medical Products Reporting Program.'' 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 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.gpo.gov/fdsys/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.

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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MedWatch: The FDA Medical Products Reporting Program—OMB Control Number 0910–0291—Extension

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, three forms (collectively known as the MedWatch forms) are available from the Agency. Form FDA 3500 is intended to be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals. 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). Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation). When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will then take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

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) represent the statutory authority for the FDA to collect mandatory adverse event reports from regulated industry on medical products once approved for marketing—to monitor the safety of drugs, biologics, medical devices, and dietary supplements. There are no laws or regulations mandating the post-market reporting for medical foods, infant formula, cosmetics, or tobacco products, and the reporting for these products is done voluntarily.

Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 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) has been codified in 21 CFR 1271.350.

Use of Form 3500 (Voluntary Reporting)

This voluntary version of the form 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 (see *https://vaers.hhs.gov*), which is jointly administered by FDA and the Centers for Disease Control and Prevention.

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/*). 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/*).

Use of Form 3500B (Consumer Voluntary Reporting)

This voluntary version of the form may be used 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 of suspected serious adverse outcomes and other product problems associated with human medical products, (*https://www.fda.gov/Safety/ReportaProblem/default.htm*). Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler, the program has been promoting and facilitating voluntary reporting by both the general public and healthcare professionals. 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) 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.

Since 2013, FDA has made available Form FDA 3500B. It was proposed during the previous authorization in 2012 and is a version of Form FDA 3500 that is 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/*). 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/*).

I. Use of Form FDA 3500A (Mandatory Version)

A. 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 the 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 the 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.

B. 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, December 22, 2006), which became law on December 22, 2006. The law requires manufacturers, packers, and distributors of nonprescription, over-the-counter (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.

C. 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 Form 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.

D. 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 21 CFR part 803 (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.

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

General changes—The proposed modifications to Forms FDA 3500 and 3500A reflect changes that will bring the form into conformance, since the previous authorization in 2015, with current regulations, rules, and guidances.

The proposed extension to Forms FDA 3500, 3500A, and 3500B will only have changes in the form instructions to provide clarity of reporting. The proposed changes are regulatory driven, improving the Centers' work, and improving report processing. The Agency welcomes comments about translation of Form FDA 3500B (consumer) into Spanish and other languages.

Formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center/FDA Form/21 CFR section	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 min)	9,720
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80, 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 min)	3,454
Form 3500A (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 min)	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 min)	26
All Centers:					
Form 3500B	13,750	1	13,750	0.46 (28 min)	6,325
Total					909,395

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

The burden estimates have not changed from the current approval.

Dated: March 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05337 Filed 3–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0976]

Arthritis Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Arthritis Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on April 23, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–0976. The docket will close on April 20, 2018. Submit either electronic or written comments on this public meeting by April 20, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 20, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 20, 2018. 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.

Comments received on or before April 9, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.