to minimize the ability to identify specific products and the impact of any such strategies. Such strategies might include making available certain data from a random sample or appropriately chosen subset of subjects, restricting the data fields made available or pooling data where possible from studies of multiple members of a product class, without identifying the specific product.

For the purposes of this notice, de-identified data refers to data that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. Cf. 45 CFR 164.514(a) (although FDA references the standard used in the Privacy Rule here, the Agency notes that it is not a covered entity for the purposes of that Rule). The Agency has an unwavering commitment to protecting the privacy of research subjects' identities. As such, consistent with FDA's regulations at 21 CFR 20.63(a), any data that might be made available under this proposal would be stripped of any information which could identify patients or research subjects, either directly or through combination with other publicly available information. See id. (''The names and other information which would identify patients or research subjects . . . shall be deleted before the record is made available for public disclosure.'') This same regulation also directs outside parties to remove such personal identifiers from records prior to submission to FDA. (See § 20.63(b).)

De-identified and masked data could be used to advance public health. For example, a model of disease progression in control arms of future studies could be based on pooled control group data from past studies of the same disease or indication and would not require identification of a product or even product class nor would there be personal identifiers associated with the data. Similarly, characterization of risk factors might only involve control group data. On the other hand, validating a biomarker as a surrogate for a clinical outcome or as a predictive classifier of potential treatment response might require identification of products by class or analysis across a class to show consistency.

We note that this proposal contemplates the availability of certain data after appropriate steps have been taken to de-identify it and remove the data's link to a specific product, study, or application. This proposal does not pertain to unmasked safety and effectiveness data, (i.e., data that can be linked to a specific, identified application) including full study reports; the circumstances under which this information is disclosed is already specifically set forth in the Federal Food Drug and Cosmetic Act and FDA's regulations. Further, FDA will not make available business-related confidential commercial information contained in product applications, including but not limited to information concerning licensing agreements and information identifying suppliers, unless such information has already been publicly disclosed by the sponsor. Nor will the Agency make available trade secret information under this proposal. Such information will continue to be treated in a manner consistent with sections 301(j), 505(*l*), 520(c), 535(d), and 537(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j), 351(*l*), 360j(c), 360*ll*(d), and 360nn); the Trade Secrets Act (18 U.S.C. 1905); and FDA's regulations (21 CFR 20.61, 314.430, 601.51, and 814.9).

II. Request for Comments

FDA is interested in receiving comments from the public on the following topics: (1) What factors should be considered in masking study data (e.g., data fields from regulatory submissions to remove or modify, number of different products to pool within a product class), (2) what limitations, if any, should there be on the Agency's ability to make available the masked data as described previously, (3) are there any additional factors FDA should consider in de-identifying data in addition to FDA's requirement to remove any names and other information (e.g., birth date, death date, local geographic information, contact information) which would identify patients or research subjects before disclosing information, (4) would regulatory changes facilitate implementation of such a proposal, and if so, what changes would be most useful, and (5) which situations do you believe disclosing masked data would be most useful to advance public health?

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 the question your comment addresses by the number assigned to that question. 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. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Hamburg, M. A. and J. M. Sharfstein, ''The FDA as a Public Health Agency,'' *New England Journal of Medicine,* 2009 June 11; 360(24):2493–5.

2. Chen J., J. Florian, W. Carter, et al. ''Earlier Sustained Virologic Response End Points for Regulatory Approval and Dose Selection of Hepatitis C Therapies.'' *Gastroenterology,* 2013 March 4 *http://www.sciencedirect.com/science/article/pii/S0016508513002886*

3. Dieterle, F., et al., ''Renal Biomarker Qualification Submission: A Dialog Between the FDA–EMEA and Predictive Safety Testing Consortium,'' *Nature Biotechnology,* 2010 May; 28(5):455–62.

Dated: May 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13083 Filed 6–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 23, 2013, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm.

1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On July 23, 2013, during the morning session, the committee will discuss supplemental biologics license application (sBLA) 125057, HUMIRA (adalimumab) injection, by AbbVie Inc., for the proposed indication of reducing signs and symptoms in adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation by elevated C-reactive protein or magnetic resonance imaging, who have had an inadequate response to, or are intolerant to, a nonsteroidal anti-inflammatory drug.

During the afternoon session, the committee will discuss sBLA 125160, certolizumab injection, by UCB, Inc., for the proposed indication of treatment of adult patients with active axial spondyloarthritis, including patients with ankylosing spondylitis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 8, 2013. Oral presentations from the public will be scheduled between approximately 10:35 a.m. to 11:05 a.m., and 3:45 p.m. to 4:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 27, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 28, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 28, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–13082 Filed 6–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0212]

Tobacco Product Analysis; Scientific Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products, is announcing a scientific workshop to obtain input on the chemical analysis of tobacco products. The analyses of tobacco products include developing test methods and evaluating method performance to ensure the results of the analyses are reliable and accurate. This scientific workshop will focus on understanding the testing of tobacco filler and smoke from cigarettes, roll-your-own (RYO) tobacco, and smokeless tobacco products for specific chemicals. FDA is also opening a public docket to receive comments on these topics.

Dates and Times: The public workshop will be held on July 30, 2013, from 8:30 a.m. to 5:30 p.m., and on July 31, 2013, from 8:30 a.m. to 4 p.m. Individuals who wish to attend the public workshop must register by close of business on July 1, 2013. Submit either electronic or written comments to the docket by September 30, 2013.

Location: The public workshop will be held at 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373.

Contact Person: Janie Kim, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 1–877–287–1373, FAX: 240–276–3761, email: *workshop.CTPOS@fda.hhs.gov.*

Registration to Attend the Workshop and Requests for Oral Presentations: If you wish to attend the workshop, make an oral presentation at the workshop, or view the free webcast, you must register by submitting an electronic or written request by July 1, 2013. Please submit electronic requests to *http://surveymonkey.com/s/3RGVYFT.* A confirmation email will be sent to your registered email at least 2 weeks prior to the workshop date. Those without email access may register by contacting Janie Kim (see *Contact Person*). Please provide contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free, but early registration is recommended because seating is limited. FDA may limit the number of participants from