



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Advisory Committee Nominations; Modification to Process for Collecting and Posting Curricula Vitae

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is modifying the process by which we collect and post curricula vitae (CVs) of advisory committee members so that the CVs will be posted to our Web site without removing or redacting any information. Posting CVs without removing or redacting any information will increase the transparency of FDA's selection of officials who serve on advisory committees, and will ensure greater public access to the qualifications of advisory committee members on an ongoing basis. Because advisory committee members are best situated to determine whether there is confidential information in their CVs, this modified collection and posting process will conserve FDA resources because FDA personnel will no longer be responsible for reviewing and redacting the CVs.

DATES: All nominees for positions on an FDA advisory committee will be required to submit a consent form on or after the date of the Office of Management and Budget (OMB) approval for this information collection, authorizing FDA to publicly post an un-redacted copy of their CV on FDA's Web site. Elsewhere in this issue of the Federal Register, FDA is publishing the notice for the proposed information collection. Additionally, effective [INSERT DATE 30 DAYS

AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], all existing advisory committee members who submit an updated version of their CV to FDA will be required to submit a consent form along with their CV.

FOR FURTHER INFORMATION CONTACT: Questions should be sent electronically to ACOMSSubmissions@fda.hhs.gov, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002.

SUPPLEMENTARY INFORMATION:

I. Background

FDA generally has posted the CVs of FDA advisory committee members publicly on <http://www.fda.gov/AdvisoryCommittees/> after reviewing the CVs and redacting information that appeared to be confidential. Currently, FDA requires the submission of a CV for each nominee as part of the nomination process for advisory committee members. FDA also requests that existing advisory committee members submit updated versions of their CVs, typically on a yearly basis.

In furtherance of FDA's goal of ensuring transparency regarding the qualifications of individuals selected to serve on FDA advisory committees, and in recognition that individual advisory committee members are best situated to evaluate the confidentiality of information contained in their CVs, including any considerations raised by their relationships and agreements with third parties, FDA will be requiring that all CVs submitted as part of the nomination process for positions on FDA advisory committees be accompanied by a written consent form stating that, if the nominee is accepted as a member of an FDA advisory committee, the individual consents to the publication of the individual's CV to FDA's Web site, without FDA removing or

redacting any information. The consent form requires that the nominee affirm that the CV does not include any confidential information, including information pertaining to third parties that the nominee is not permitted to disclose. A nominee will be required to submit a signed consent form in order for the nomination to be considered complete. The consent form will need to be submitted along with the four other types of documents currently requested as part of the nomination process: (1) A CV for each nominee; (2) a written confirmation that the nominee is aware of the nomination (unless self-nominated); (3) a letter(s) of recommendation; and (4) for Consumer Representative applications, a cover letter that lists consumer or community organizations for which the candidate can demonstrate active participation. In addition to the consent form submitted as part of the application process, FDA will also be requiring that a nearly identical consent form be submitted by all existing advisory committee members each time they submit an updated version of their CV to FDA. The language of the consent for existing advisory committee members will differ only in that it will not include the language “if [the nominee is] selected to serve on an [FDA] advisory committee”.

Every day, FDA makes important health and safety decisions about foods, drugs, medical devices, cosmetics, and other widely used consumer products. Transparency in FDA’s activities and decision making allows the public to better understand the Agency’s decisions, increasing credibility and promoting accountability. Transparency helps the Agency to more effectively protect and promote the public health. Ensuring greater public awareness of the qualifications of individuals responsible for assisting the Agency in making important policy decisions is an important factor in ensuring such transparency. Posting the CVs of advisory committee members helps increase public awareness. Additionally, requiring advisory committee nominees and advisory committee members to attest that their CVs do not include any confidential

information, including information pertaining to third parties that they are not permitted to disclose, will help conserve limited FDA resources by ensuring that the individual most familiar with the information contained in the CV, as well as any contractual or confidentiality agreements that might affect their ability to disclose that information, assumes the responsibility for determining whether the information may be released publicly. Because advisory committee nominees and members are most familiar with the information contained in their CVs, FDA will not be advising potential or current members about whether specific information in their CVs is confidential or otherwise should be removed.

II. Advisory Committee Member CVs and Confidential Information

The consent form will be required to be submitted each time an advisory committee nominee's or existing advisory committee member's CV is submitted to FDA. All information contained in the CV submission for individuals who are selected for or currently serving on an FDA advisory committee will be available for public posting. Specifically, for nominees for positions on an FDA advisory committee, the required consent will state as follows:

If I am selected to serve on an advisory committee, I consent to publication of my curriculum vitae (CV), and any subsequent updates to my CV that I provide FDA, on FDA's Web site, without removing or redacting any information. My CV does not include any confidential information, including information pertaining to third parties that I am not permitted to disclose.

For existing advisory committee members who submit updated CVs, the required consent will state as follows:

I consent to publication of my curriculum vitae (CV), and any subsequent updates to my CV that I provide FDA, on FDA's Web site, without removing or redacting any

information. My CV does not include any confidential information, including information pertaining to third parties that I am not permitted to disclose.

III. Date of Implementation

All nominations for new advisory committee members will be required to be submitted through FDA's Web site at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, or any successor system, and the submission will be required to be accompanied by the required consent form, on or after the date of OMB approval for this information collection. All updated CVs for existing advisory committee members will be required to be submitted to FDA along with the required consent form after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: February 1, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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