4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3230]

Consumer Comments-Public Posting and Availability of Comments Submitted to Food and Drug Administration Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is changing the Agency's long standing practice of not publically posting on http://www.regulations.gov comments submitted by individuals in their individual capacity. These are generally comments from people who self-identify as an "individual consumer" under the field titled "Category (Required)" on the "Your Information" page on http://www.regulations.gov. Changing FDA's practice to routinely post these comments, as we do other comments, will increase the transparency and public utility of FDA's public dockets. It will better enable our public dockets to function as intended: to share information and encourage an open exchange of ideas.

DATES: All comments submitted to any FDA docket on or after October 15, 2015, will be publically posted, unless otherwise determined not to be subject to posting as described in the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Cohen, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3324, Silver Spring, MD, 20993-0002, 301-796-7001.

SUPPLEMENTARY INFORMATION:

I. Background

Historically, FDA generally has not publicly posted on http://www.regulations.gov comments submitted by individuals in their individual capacity (and not on behalf of an organization, corporation, or other entity). For comments submitted through http://www.regulations.gov, for example, such comments are identified as "Individual Consumer" under the field titled "Category (Required)" on the "Your Information" page. This non-posting practice has applied only to individual consumer comments which otherwise would be displayed on http://www.regulations.gov. These comments have been placed in the official FDA docket and are publicly available in FDA's Reading Room or through Freedom of Information Act requests and have been considered by the Agency in finalizing its regulatory actions.

FDA is changing this practice and will post such consumer comments on http://www.regulations.gov, as it posts other comments. FDA has made this change so that its public dockets better serve their purpose of promoting transparency and the sharing of information.

In 1995, FDA explained that it routinely reviewed all comments for obvious confidential information before placing the comments in the docket (60 FR 66982), but this practice is no longer feasible given factors such as the volume of comments FDA receives and the adoption of a government-wide electronic portal system for submitting and posting comments at

http://www.regulations.gov. FDA developed the practice of not posting individual consumer comments largely because of concerns about disclosing personal information of individuals who may not have realized, when submitting their comments, that their name, address, and other identifying information would be publicly viewable. This public viewability became more obvious as the Internet gained popularity and particularly when FDA dockets system was merged with the government-wide portal system for submission of all public comments on government regulatory actions at http://www.regulations.gov in 2007. This practice has been precautionary because, as FDA has stated previously, "there can be no reasonable expectation of confidentiality for information submitted to a public docket in a rulemaking proceeding[1]." With the advent of http://www.regulations.gov, FDA selected "individual consumer" comments for non-posting because of previous concerns raised by individuals and the conclusion that such commenters may not be as familiar with the regulatory process and the public nature of dockets as are other entities, such as regulated industry.

In recent years, FDA has occasionally made exceptions to this non-posting practice, typically using the COMMENTS section in a particular Federal Register document to alert the public that all comments were subject to public posting. FDA Federal Register documents, requesting or providing for the submission of comments, published subsequent to this notice will contain new instructions and information concerning the posting of comments submitted to that particular docket.

This change fulfills a recommendation from the 2010 FDA Transparency Initiative[2] and aligns with a 2013 recommendation from the Administrative Conference of the United States

[1] 60 FR 66981, at 66982 (December 27, 1995).
[2] "FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration," May 2010, available at www.fda.gov/AboutFDA/Transparency/PublicDisclosure (p. 4).

that "[a]gencies should manage their public rulemaking dockets to achieve maximum public disclosure" consistent with legal limitations and other claims of privilege[3]. It also furthers an objective in Executive Order 13563[4], which directs Agencies to base their regulations on "public participation and an open exchange of ideas."

II. Consumer Comments and Confidential Information

The commenter is solely responsible for ensuring that the submitted comment does not include any confidential information that the commenter or a third party may not wish to be posted, such as private medical information, the commenter's or anyone else's Social Security number, or confidential business information, such as a manufacturing process. If a name, contact information, or other information that identifies the commenter is included in the body of the submitted comment, that information will be posted on http://www.regulations.gov. FDA will post comments, as well as any attachments submitted electronically, on http://www.regulations.gov, along with the State/Province and country (if provided), the name of the commenter's representative (if any), and the category selected to identify the commenter (e.g., individual, consumer, academic, industry).

The Agency expects that only in exceptional instances would a comment need to include private, personal, or confidential information. If a comment is submitted with confidential information that the commenter does not wish to be made available to the public, the comment would be submitted as a written/paper submission and in the manner detailed in the applicable Federal Register document. For written/paper comments submitted containing confidential information, FDA will post the redacted/blacked out version of the comment including any attachments submitted by the commenter. The unredacted copy will not be posted, assuming the

[3] Recommendation No. 2013-4, available at http://www.acus.gov/recommendation/administrative-record-informal-rulemaking.
[4] Executive Order 13563, available at http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf

commenter follows the instructions in the applicable Federal Register document. Any information marked as confidential will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

FDA will include new information and standard instructions for submitting comments in all Federal Register documents requesting or providing for the submission of comments. The instructions will explain how to submit comments to the docket on that particular document via electronic means and also will explain the process for submission of comments, in written/paper format, that the commenter wishes to mark as confidential.

III. Date of Implementation

All comments submitted electronically through http://www.regulations.gov to any FDA docket, existing or new, after October 15, 2015, will be posted to the applicable docket and publicly viewable on http://www.regulations.gov. All comments submitted by mail or delivery to the Division of Dockets Management in written/paper format to any FDA docket, existing or new, after October 15, 2015, will be posted to the applicable docket and publicly viewable on http://www.regulations.gov unless submitted under the following conditions: 1) The written/paper submission is marked as confidential, and 2) the submitter provides an unredacted and a redacted version; the redacted version must have the information claimed as confidential redacted/blacked out. If submitted under these conditions, only the redacted/blacked out written/paper submission will be posted publicly on http://www.regulations.gov, except as otherwise provided by § 10.20 or other law.

Dated: September 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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