UNITED STATES FOOD AND DRUG ADMINISTRATION

Applications for FDA Approval to Market a New Drug

OMB Control No. 0910-0001

Request for Non-Substantive, Non-material Change to Form FDA 2253

Form FDA 2253 entitled, "*Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use*," is an electronic form approved in OMB control no. 0910-0001, and is presently used to collect requisite data elements for submissions of advertising and promotional labeling for products approved under new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologic license applications (BLAs). This information is required under 21 CFR 314.81, 21 CFR 314.98, and 21 CFR 601.12. Currently, the field denoting application type provides respondents with four options from which to make a designation, which FDA uses to further direct and process the submissions internally. We are seeking to revise the form to include an additional application-type option for certain submissions made as required by conditions of Emergency Use Authorizations (EUAs), governed by section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA). (Information collection associated with section 564 of the FFDCA is approved in OMB control no. 0910-0595, and includes reporting by manufacturers of unapproved EUA products.)

Specifically, we are seeking to add the selection "CDER IND" to the application-type menu of Form FDA 2253. With an EUA, FDA often establishes conditions of authorization that include requirements pertaining to advertising and promotional materials. Similar to the requirements for drugs and biologics under the above-cited regulations governing approved NDA, ANDA and BLA products, one such condition of authorization of an EUA, under section 564(e) of the FFDCA, may require that all descriptive printed matter, advertising, and promotional material for certain drugs and biological products be submitted to FDA along with the Form FDA 2253 at the time of initial dissemination or first use. Because the current Covid-19 pandemic has resulted in the issuance of an increased (and still increasing) number of EUAs, many of which include this condition of authorization, and because we currently have no systematic way to capture this information, we are proposing to expand the utility of Form FDA 2253. We will continue to account for information collection under section 564 of the FFDCA in OMB control no. 0910-0595; however, revising Form FDA 2253 as proposed would provide a choice for categorizing submissions of descriptive printed matter, advertising, and promotional material for EUAs in a manner analogous to that used for submissions made for drug and biologic products subject to approved NDAs, ANDAs, and BLAs and apply to the same respondents. Adding the additional application-type designation also enables us to more efficiently manage these incoming submissions and capture the required information. As our experience using EUAs continues to evolve amid the current public health crisis, we continue also to consider processes that will maximize existing resources and facilitate the submission of information for respondents. We have made no adjustment to our burden estimate in OMB control no. 0910-0001 to reflect this functional change to Form FDA 2253. Rather, as we are currently underway with our renewal of OMB control no. 0910-0595, we are evaluating necessary adjustments to our burden estimates associated with information collection found in section 564 of the FFDCA.

Submitted: September 2021