UNITED STATES FOOD & DRUG ADMINISTRATION

Applications for FDA Approval to Market a New Drug

OMB Control No. 0910-0001

Request for change: New Form FDA 3938: DRUG MASTER FILE FORM

This change request supports implementation of a new form. As provided for in 21 Code of Federal Regulations (CFR) Part 314.420(a), a drug master file (DMF) is a submission of information to the Food and Drug Administration by a person (the DMF holder) who intends it to be used for one of the following purposes: to permit the holder to incorporate the information by reference when the holder submits an investigational new drug application under part 312 or submits an application or an abbreviated application or an amendment or supplement to them under part 314 or a biologics license application under section 351(a) of the Public Health Service Act; or, to permit the holder of the DMF to authorize third parties to reference the information to support a submission to FDA without the DMF holder having to disclose the information to the third party.

Form FDA 3938 has been designed for submission with new DMFs, all DMF amendments, and any correspondence requesting changes of information within the DMF. Its purpose is to clearly identify DMF Holder and Agent information, and to facilitate submission and archive of DMF correspondence in electronic format. The information collected includes the name of the organization, DMF holder, DMF agent, contact information, type of DMF, submission type (original or amendment), establishment information, and certifications. These data elements are provided for by our new drug application regulations, approved under OMB Control No. 0910-0001. We believe use of the form will improve efficiency in collecting and using the data and helps identify, verify, and archive documents in each DMF submission. The form is to be made available for electronic submission. We believe the form allows for a more streamlined approach for accepting data.

We anticipate using Form FDA 3938 will require less than 1 hour for respondents to complete, however we believe this burden is offset by the current practice of submitting a cover letter. Consistent with our Good Guidance Practice (GGP) regulation in 21 CFR 10.115, we developed the draft guidance document, "*Drug Master Files: Guidance for Industry,*" (inviting public comment October 21, 2019 (84 FR 56194)) and communicate to respondents that we intend to develop a form to replace the need for the DMF holder to create a cover letter for submitting the information data elements.

Submitted: January 2020