U.S. FOOD & DRUG ADMINISTRATION

REQUEST FOR NON-SUBSTANTIVE/NON-MATERIAL CHANGE:

We are requesting non-substantive/non-material changes to **OMB Control Nos. 0910-0001** (*Applications to Market a New Drug*); **0910-0014** (*Investigational New Drug Applications*); and **0910-0338** (*Biologics License Applications*) to modify forms used by respondents in support of submissions to the agency. Both forms support programs funded by user fees under the Prescription Drug User Fee Act (PDUFA), most recently authorized in August 2017 and imminently expiring in September 2022. Since early in 2021, FDA has engaged with interested stakeholders on various aspects of the next PDUFA authorization, expected in August-September 2022. We maintain a resource page on our website that communicates updates to stakeholders with regard to reauthorization activities and the upcoming enactment of PDUFA VII. See https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments. Although originally developed in a paper-based format, Forms FDA 356h and 1571 are now submitted in an electronic format as fillable PDFs found at https://www.fda.gov/about-fda/reports-manuals-forms/forms through a web-based application process. As a result of these updates, however, we are making no adjustment to our current burden estimates.

Form FDA 356h; Application to Market a New or Abbreviated New Drug or Biologic for Human Use, is used by respondents to submit New Drug Applications, Abbreviated New Drug Applications, or Biologics License Applications. **Form FDA 1571; Investigational New Drug Application (IND),** is used by respondents to submit Investigational New Drug Applications.

We are intending the following changes, as reflected in the attached PDFs denoting/highlighting the proposed modifications:

Current Form 356h:	**Proposed**
Form Box 6	Replace "Authorized U.S. Agent Name" with "U.S. Agent Company", "Prefix", "First Name", "Middle", "Last Name", and "Title".
Form Box 21	Add new check box for Human Factors (Specify Type: _____) Add new check box for REMS Assessment Methods and Study Protocols Add new check box for REMS Assessment Report
Form Box 25	Add a new yes/no check box for Digital Health Technologies (DHT) Data Delete the box containing the words “Human Factors Information?”
Form Box 28	Add a new field “Is this establishment involved in the change described in this supplement? Yes/no”
Form Box 28	Replace "Name of Contact for the Establishment" with "Prefix", "First Name", "Middle", "Last Name", and "Title".

Current Form 356h:	Proposed
Form Box 29	Replace "BMFs, MAFs, and DMFs" with “MFs, DMFs, and MAFs”.
Form Box 31	Replace "Typed Name and Title of Applicant’s Responsible Official" with "Applicant’s Responsible Official" (section header), "Prefix", "First Name", "Middle", "Last Name", and "Title”.
Instructions for completing the form	Made changes related to items noted above, and other clarifying instructions.

Current Form FDA 1571	Proposed Change
Form Field 1	Add new check box for CDER/CBER Assignment of IND
Form Field 11	Change to 11a. Add new check box for Use-Related Risk Analysis under Protocol Amendment Add Field 11b: Does the submission contain: Digital Health Technology (DHT) data or a proposal to collect yes/no
Form Field 15	Update the 21 CFR reference from 21 CFR 312.3(b) to 21 CFR 312.52
Form Field 18	Replace "Name of Sponsor or Sponsor’s Authorized Representative" with " Sponsor or Sponsor’s Authorized Representative" (section header), "Prefix", "First Name", "Middle", "Last Name", and "Title”.
Instructions for completing the form	Made changes related to items noted above, and other clarifying instructions.

Attachments:

Form FDA 1571 pdf with denoted changes
Form FDA 1571 Instructions pdf with denoted changes
Form FDA 356H with denoted changes
Form FDA 356H Instructions pdf with denoted changes

Submitted: September 2022