

FOOD AND DRUG ADMINISTRATION
Non-substantive Change Request
OMB Control Nos. 0910-0167
Orphan Drugs

Date Submitted: April 15, 2025

Summary of request: The Food and Drug Administration is requesting a change request to revise questions to align with Executive Order (EO) 14168 *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*.

Description of Changes Requested: Remove the prefix “Mx.” from the fields “Primary Contact Prefix” and “Sponsor U.S. Resident Agent Prefix” to be in accordance with EO 14168.

☒ Revision of an existing question(s)

☐ Deletion of an existing question(s)

Description of Changes to Burden (if applicable):

N/A: No change in burden

Attachments:

Document	Tracked Changes Version	Clean Version
Form FDA 4035	 Form%204035_edit %20draft.docx	 Form%204035_edit %20clean.docx