

**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