Small Biotech ICR Crosswalk of Changes Between 60-Day Notice and 30-Day Notice

Location of Edits	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
Supporting Statement (throughout), Small Biotech Information Collection Request Form (throughout)	• Revisions to terminology, for consistency with the program guidance issued during the 60-day comment period, and to further explain which entities may benefit from submitting the information collection consistent with the program guidance issued during the 60-day comment period	Modify / Add	Technical update
Supporting Statement (Use of Information Technology)	• Revised backup method from mail to e-mail for information submission	Modify	Policy change for beneficial alignment with the goal of using information technology
Supporting Statement (throughout), Small Biotech Information Collection Request Form (throughout)	• Revised language to limit collection of information on members of a controlled group to members that had a Coverage Gap Discount Program agreement in effect on December 31, 2021	Modify	Policy change in response to comments
Supporting Statement (Federal Register / Outside Consultation)	• Revised language consistent with publishing a revised package for a 30-day public comment period and for added specificity	Add	Technical update
Supporting Statement (Cost to the Federal Government, Changes to Burden)	• Corrected the job series number for General Operations Manager • Revised federal burden estimate to include communications with Submitting Manufacturers	Modify, Add	Technical correction; modified cost to the federal government in response to comments
Supporting Statement (Use of Information Technology), Small Biotech Information Collection Request Form (Question 2)	• Added questions to capture the active moiety / active ingredient and New Drug Applications (NDAs) / Biologics License Applications (BLAs) for the qualifying single source drug for which the Submitting Manufacturer is seeking the Small Biotech Exception	Add	Additions to enable the Submitting Manufacturer to more precisely identify the qualifying single source drug for which it is seeking the Small Biotech Exception consistent with the program guidance issued during the 60-day comment period
Supporting Statement (Use of Information Technology, Burden Estimate), Small Biotech Information Collection Request Form (throughout)	• Revised language describing who can certify a submission	Modify	Technical update since data will be separately collected in HPMS registration processes

	• Removed table with contact information (name, title, telephone number, e-mail, signature, and date) for person responsible for submission		