**Centers for Medicare & Medicaid Services Response to Public Comments Received for CMS-10844, OMB 0938-1443**

**Request for a Biosimilar Delay**

**Comment:** A commenter noted that the 30-day submission window for the biosimilar initial delay requests may not provide biosimilar manufacturers enough time to prepare and submit requests as they cannot predict when OMB may approve the proposed information collection request. The commenter also suggested that CMS provide notice to the Reference Drug manufacturer when a biosimilar delay request is submitted.

**Response:** CMS thanks the commenter for their feedback. Consistent with CMS' response to similar comments in the final guidance for initial price applicability year 2027 and initial price applicability year 2028, the timing for the submission of a request for a biosimilar delay in accordance with section 1192(f) of the Act and proposed at § 429.110 and is based on a set timeline in the statute and operational constraints related to the drug selection process. CMS reiterates that it must make a full determination and may not immediately delay the selection of a Reference Drug whilst making a complete determination of the requirements specified in section 1192(f) of the Act and proposed at § 429.110 to determine the outcome of a request to delay the inclusion of a Reference Drug by one initial price applicability year (an "Initial Delay Request"). Further, the deadline for an Initial Delay Request has been set as close to the selected drug publication date as is administratively feasible. CMS adopted this timeline under the authority granted to it in section 1192(f)(1)(B)(ii) of the Act to set the time, form, and manner of Biosimilar Delay requests, and has exercised this authority to establish a timeline (which is described in sections 30.3.1 and 30.3.1.1 of the final guidance) that allows CMS to carefully review the Initial Delay Request documentation and, if applicable, to request follow-up information from the manufacturer of a biosimilar (the "Biosimilar Manufacturer") on its Initial Delay Request.

**Identification and Selection of a Renegotiation-Eligible Drug**

**Comment:** A commenter expressed support for making the Drug Selection ICR voluntary for the Primary Manufacturer to provide input to inform renegotiation eligibility and selection.

**Response:** We thank this commenter for their support.

**Comment:** A commenter requested that CMS increase the word count for Questions 15 and 16 and allow for submission of supporting documentation such as charts or graphs. The commenter stated that the 36,000 character limit (approximately 3,000 words) may not be sufficient to provide comprehensive information, for example in situations where a selected drug has multiple indications.

**Response**: We appreciate the commenter's feedback. Consistent with our response to a similar suggestion in the initial price applicability year 2028 version of this ICR, we reiterate that the instructions for Questions 15 and 16 indicate responses should be limited to "new information or

evidence" since the date of the previously agreed-upon maximum fair price (MFP) for the selected drug. Therefore, we believe that that the 36,000-character count (approximately 3,000 words) is sufficient. We also note that both Question 15 and 16 provide for the opportunity to submit up to five visual representations (which may include charts and graphs) in addition to submitting up to 25 citations of new evidence for each question.