UNITED STATES FOOD & DRUG ADMINISTRATION

Postmarketing Adverse Event Reporting for Medical Products
and Dietary Supplements During a Pandemic

OMB Control No. 0910-0701

JUSTIFICATION MEMORANDUM FOR NON-SUBSTANTIVE CHANGE REQUEST

The Food and Drug Administration (FDA, the agency) is requesting a nonmaterial/non-substantive change to OMB control number 0910-0701. We have revised the currently approved collection instrument to apply to any pandemic and not specifically an influenza pandemic. The revised final guidance document is entitled, "*Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic*." The guidance discusses our recommendations on adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic. Because of the potential for high employee absenteeism during an influenza pandemic and because responsibility to report adverse events during such a pandemic remained in effect, the guidance is intended to help firms meet adverse event reporting requirements under these circumstances.

Specifically, the guidance document provides our recommendations on focusing limited resources to certain types of reports, including planning, notification, and documentation of postmarketing adverse events and on each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes.

In response to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE), we updated the Final Guidance in March 2020. The primary revision was to remove the word "influenza" so that the recommendations apply to any pandemic.

Dated: June 2020