

UNITED STATES FOOD & DRUG ADMINISTRATION

Shortages Data Collection

OMB Control No. 0910-0491

Request for non-substantive, non-material change to an approved information collection:

Added by section 3112 of the Coronavirus Aid, Relief, and Economic Stability Act (CARES), FDA is requesting to include information submitted under section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) with the information collection. Section 506J of the FD&C Act (21 USC 356j) requires manufacturers to notify FDA, during or in advance of a public health emergency, of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States. To implement this provision we have updated our electronic medical device registration system to include data elements required under section 506J and have created a user guide to assist respondents with submission of notifications. As communicated on our website, respondents not certain whether to notify FDA about a particular device or interruption may contact FDA by e-mail at CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH, or cbershortage@fda.hhs.gov for devices regulated by CBER.

Attachments:

How to Use the Section 506J Template (August 2021)

21 USC 356j