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Docket: FDA-2014-N-1960
Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

Comment On: FDA-2014-N-1960-0001
Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

Document: FDA-2014-N-1960-DRAFT-0003
Comment from Linda Bowen, Sanofi

Submitter Information

Name: Linda Bowen
Organization: Sanofi

General Comment

See attached

Attachments

Signed comment FDA-2014-N-1960

09 February 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2014–N–1960

Request for comments: Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The FDA Medical Products Reporting Program

Dear Sir/Madam:

Reference is made to the Federal Register Notice of 11 December 2014 (79 FR 73591) announcing a call for comments on FDA's proposed collection of information on their Medical Products Reporting Program (MedWatch).

Sanofi, an integrated global healthcare leader that discovers, develops and distributes therapeutic solutions focused on patients' needs, appreciates the opportunity to provide feedback and offers the following:

Comment 1: Page 73594 Section B. Changes Proposed for Form FDA 3500; Page 73594 Section C. Changes Proposed for Form FDA 3500A; and Page 73595 Section D. Changes Proposed for Form FDA 3500B

We recommend the option of a check box for race/ethnicity **unknown.**

Comment 2:
We recommend an implementation date eighteen (18) months after publication of the finalized form.

Sincerely,

Linda Bowen

Linda Bowen, MS, RAC, FRAPS
Head of U.S. Regulatory Policy and Intelligence