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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-0002
Comment from Kathleen O'Neill, NA

Submitter Information

Name: Kathleen O'Neill
Organization: NA

General Comment

Please see attached file.

Attachments

Cover Letter for Comments Docket FDA-2014-N-1960

<February 3, 2015>

Department of Health and Human Services
Division of Dockets Management, Food and Drug Administration
5630 Fishers Lane
Room 1061
(HFA – 305)
Rockville, Maryland 20852

Re: FDA Agency Information Collection Activities; Proposed Collection; Comment Request<MedWatch: The Food and Drug Administration Medical Products Reporting Program> (Docket No. FDA-<2014-N-1960>)

Dear Sir or Madam,

Baxter International Inc. ("Baxter") is pleased to have this opportunity to submit comments to Docket No. FDA-<2014-N-1960>, *FDA Agency Information Collection Activities; Proposed Collection; Comment Request; <MedWatch: The Food and Drug Administration Medical Products Reporting Program>* Baxter International Inc., through its subsidiaries and approximately <61,500> employees, develops, manufactures and markets products that save and sustain the lives of people with <hemophilia, immune disorders,> infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

We appreciate the opportunity to comment on this draft guidance and provide these recommendations for your consideration. We respectfully submit the following comments:

Field/Section of form	Proposed Change	Rationale
Section G Field 4 and Section C Field 6	We propose to add a third checkbox labeled "unknown" for when this type of information is not received	This information may not be received
General	We propose that the FDA require medical device adverse reporting use the MedDRA dictionary instead of the Patient Problem Codes	Currently when reporting adverse events for medical devices, the current dictionary used is the "Patient Problem Codes of the Center for Devices and Radiological Health". This dictionary is much smaller (~800 terms) than the widely used MedDRA dictionary used when reporting adverse events with drugs (~20.6K terms). Using the MedDRA dictionary in place of the Patient Problem Codes would allow for more

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		accurate recording of patient adverse events.

Thank you for the opportunity to provide comments to this notification. If you have questions, please do not hesitate to contact me at <224-270-4196> or <Kathleen_O'Neill@Baxter.com>

Respectfully submitted,

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