is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The Agency has estimated that on average 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures under § 803.17 to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered “usual and customary” under 5 CFR 1320.3(b)(2).

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1.5 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.


Leslie Kux,
Acting Assistant Commissioner for Policy.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs.” The draft guidance is intended to assist manufacturers of PET drugs in submitting investigational new drug applications (INDs).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 14, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993, 301–796–2050.

FOR FURTHER INFORMATION CONTACT:
Kyong (Kaye) Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993, 301–796–2050.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0081]

Draft Guidance on Investigational New Drug Applications for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.