section 502(b)(1) (21 U.S.C. 352(b)(1)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) appears on the label of a nonprescription drug marketed in the United States.

FDA is requesting public comment on estimates of annual submissions from these respondents, as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462) and described in the guidance. This guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) (21 U.S.C. 379aa(b)(1)) of the FD&C Act, including followup reports under 760(c)(2) (21 U.S.C. 379aa(c)(2)) of the FD&C Act, and how to submit these reports. The estimates for annual reporting burden and recordkeeping are based on FDA's knowledge of adverse drug experience reports historically submitted per year for prescription drug products and for nonprescription drug products marketed under an approved application, including knowledge about the time needed to prepare the reports and to maintain records.

FDA receives approximately 2,500 serious adverse event reports for nonprescription drug products marketed under approved applications, which comprise approximately 20 percent of the overall nonprescription drug market. Based on this experience, we estimate between 10,000 and 15,000 (*i.e.,* 12,500) total annual responses for nonprescription drugs marketed without an approved application.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Reports of Serious Adverse Drug Events (21 U.S.C. 379aa(b) and (c))	50	250	12,500	2	25,000
Total					25,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 760(e) (21 U.S.C. 379aa(e)) of the FD&C Act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance recommends that responsible persons maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports. Although the guidance does not provide recommendations on recordkeeping activities generally under section 760(e) of the FD&C Act, FDA is providing an estimate for the burden of this collection. Historically, serious adverse event reports comprise approximately two-thirds and nonserious adverse event reports comprise approximately one-third of the total number of postmarketing adverse event reports associated with drugs and biologic therapeutics (except vaccines) received by FDA. Based on this generalization, FDA estimates the total annual records to be approximately 20,000 records per year. FDA estimates that it takes 5 hours to maintain each record and the recordkeeping burden as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	5	100,000
Total					100,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: December 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33140 Filed 12–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0787]

Draft Guidance for Industry and Food and Drug Administration Staff; Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the **Federal Register** of Thursday, November, 10, 2011 (76 FR 70150). In the notice, FDA requested comments on the draft guidance that addresses the approaches FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the investigational device exemption (IDE) requirements. The Agency is taking this

action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments and information by March 9, 2012.

ADDRESSES: 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dorothy Abel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1204, Silver Spring, MD 20993–0002, (301) 796–6366.

I. Background

In the **Federal Register** of November 10, 2011 (76 FR 70150), FDA published a notice announcing the availability of the draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies'' and the opening of a public docket to receive comments on the key principles unique to the justification for, and design of, early feasibility studies, as well as outlines the general principles for preparing and reviewing early feasibility study IDE applications that are discussed in the guidance. Interested persons were invited to submit comments by February 8, 2012. At this time, the Agency is extending the comment period until March 9, 2012, to continue to receive public comments. Comments submitted to the docket will enhance the development and review of IDE applications for early feasibility studies of significant risk for the industry and the Center for Devices and Radiological Health.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33142 Filed 12–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0790]

Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff; Food and Drug Administration Decisions for Investigational Device Exemption (IDE) Clinical Investigations; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the **Federal Register** of Thursday, November, 10, 2011 (76 FR 70151). In the notice, FDA requested comments on the draft guidance that has been developed to promote the initiation of clinical investigations to evaluate the medical devices under FDA's Investigational Device Exemptions (IDE) regulations. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit written or electronic comments and information by March 9, 2012.

ADDRESSES: 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1108, Silver Spring, MD 20993–0002, (301) 796–6356.

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, (301) 827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 10, 2011 (76 FR 70151), FDA published a notice announcing the availability of the draft guidance entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations'' and the opening of a public docket to receive comments on the development of methods to allow a clinical investigation to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. Interested persons were invited to submit comments by February 8, 2012. At this time, the Agency is extending the comment period until March 9, 2012, to continue to receive public comments. Comments submitted to the docket will assist in promoting timely clinical investigations actions that the Center for Devices and Radiological Health and Center for Biologics Evaluation and Research can consider taking for IDE submissions.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33141 Filed 12–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.