Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

### Table 2—Estimated Annual Recordkeeping Burden 1

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>54.6</td>
<td></td>
<td>1</td>
<td>1,000</td>
<td>0.25</td>
<td>250</td>
</tr>
</tbody>
</table>

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

### Table 3—Estimated Annual Third-Party Disclosure Burden 1

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>54.4(b)</td>
<td></td>
<td>1</td>
<td>10,554</td>
<td>0.17</td>
<td>1,794</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with the collection of information.
GUIDANCE ON FACTORS TO CONSIDER WHEN MAKING BENEFIT-RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVAL AND DE NOVO CLASSIFICATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0577]

Guidance for Industry and Food and Drug Administration Staff; Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and de Novo Classifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications.” This guidance is intended to provide greater clarity on FDA’s decisionmaking process with regard to benefit-risk determinations in the premarket review of medical devices in the premarket approval and de novo pathways.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist in processing your request, or fax your request to 301–847–8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (see DATES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.


Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–7456 Filed 3–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0577]

Guidance for Industry and Food and Drug Administration Staff; Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and de Novo Classifications; Availability

AGENCY: Food and Drug Administration, HHS.

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