unintentional and adverse. The standard comprehensive test battery is generally sufficient to identify endocrine-related toxicity. Depending on the outcome of a standard battery of nonclinical tests, additional nonclinical studies may be warranted to more fully characterize the endocrine-related toxicity potential of a drug.

This guidance finalizes the draft guidance entitled “Endocrine Disruption Potential of Drugs: Nonclinical Evaluation” issued on September 20, 2013 (78 FR 57859). Revisions to the draft guidance address public comments and try to give more clarity regarding when additional studies could be appropriate.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on nonclinical evaluation of endocrine-related drug toxicity. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 341 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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, and will be posted to the docket at http://www.regulations.gov.

IV. 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,
Associate Commissioner for Policy.
[FR Doc. 2015–22683 Filed 9–8–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Formal Dispute Resolution: Appeals Above the Division Level; Revised Draft Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry and review staff entitled “Formal Dispute Resolution: Appeals Above the Division Level.” This guidance is intended to provide recommendations for industry and review staff on the procedures in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) for resolving scientific and/or medical disputes that cannot be resolved at the division level. This guidance describes procedures for formally appealing such disputes to the office or center level and providing information to assist FDA officials in resolving the issue(s) presented. This draft guidance revises the draft guidance of the same name issued March 13, 2013.

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 revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 8, 2015.

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, 10001 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 revised 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.

FOR FURTHER INFORMATION CONTACT: Khushboo Sharma, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 7911, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10003 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry and review staff entitled “Formal Dispute Resolution: Appeals Above the Division Level.” In the course of the review of applications for user fee products, a wide variety of scientific and/or medical issues are discussed that are critical to a sponsor’s drug product development program. Sometimes, a sponsor may disagree with the Agency on a matter, and a dispute arises. Because these disputes often involve complex scientific and/or medical matters, it is critical that there be procedures in place to help ensure open, prompt discussion of such disputes. The procedures and policies described in this guidance are intended to promote rapid resolution of scientific and/or medical disputes between sponsors and CDER or CBER.

This draft guidance revises the draft guidance of the same name issued March 13, 2013 (78 FR 15955). Based on the docket comments for the draft guidance as well as on its own initiative, FDA made the following changes. The scope of the guidance was expanded to include formal dispute resolution requests for human drug applications covered under the Biosimilar User Fee Act of 2012. Additionally, certain areas were revised to provide more clarity, such as when a matter is and is not appropriate for a formal dispute resolution request, and information to include in the supporting background information. Also, this guidance clarifies that CDER and CBER intend to manage formal requests for appeals of scientific and/or medical
disputes related to an application for a user fee product under any of the
available regulatory mechanisms (i.e.,
21 CFR 10.75, 312.48(c), 314.103(c)),
through the formal dispute resolution
process.

This revised draft guidance is being
issued consistent with FDA’s good
guidance practices regulation (21 CFR
10.115). The draft guidance, when
finalized, will represent the current
thinking of FDA on formal dispute
resolution requests for appeals above
the division level. It does not establish
any rights for any person and is not
binding on FDA or the public. You can
use an alternative approach if it satisfies
the requirements of the applicable
statutes and regulations.

II. The Paperwork Reduction Act
of 1995

This revised draft guidance refers to
previously approved collections of
information that are subject to review by
the Office of Management and Budget
(OMB) under the Paperwork Reduction
collections of information in this draft
guidance have been approved under
OMB control number 0910–0430. This
draft guidance is a revision of an earlier
version of the guidance. The revised
version contains no additional
information collections; therefore, it
continues to be covered under OMB
control number 0910–0430.

III. Comments

Interested persons may submit either
electronic comments regarding this
document to http://www.regulations.gov
or written comments to the Division of
Dockets Management (see ADDRESSES).
It is only necessary to send one set of
comments. Identify comments with the
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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, and
will be posted to the docket at http://
www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet
may obtain the document at http://
www.fda.gov/Drugs/
GuidanceCompliance
RegulatoryInformation/default.htm,
http://www.fda.gov/
BiologicsBloodVaccines/
GuidanceCompliance
RegulatoryInformation/default.htm, or

Dated: September 2, 2015.
Leslie Kux,
Associate Commissioner for Policy.
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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0908]

Agency Information Collection
Activities; Submission for Office
of Management and Budget Review;
Comment Request; Guidance for
Clinical Trial Sponsors: Establishment
and Operation of Clinical Trial Data
Monitoring Committees

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing
that a proposed collection of
information has been submitted to the
Office of Management and Budget
(OMB) for review and clearance under

DATES: Fax written comments on the
collection of information by October 9,
2015.

ADDRESSES: To ensure that comments on
the information collection are received,
OMB recommends that written
comments be faxed to the Office of
Information and Regulatory Affairs,
OMB, Attn: FDA Desk Officer, FAX:
202–395–7285, or emailed to oira_submission@omb.eop.gov. All
comments should be identified with the
OMB control number 0910–0581. Also
include the FDA docket number found in
brackets in the heading of this
document.

FOR FURTHER INFORMATION CONTACT:
FDA PRA Staff, Office of Operations,
Food and Drug Administration, 8455
Colesville Rd., COLE–14526, Silver
Spring, MD 20993–0002, PRAStaff@
 fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In
compliance with 44 U.S.C. 3507, FDA
has submitted the following proposed
collection of information to OMB for
review and clearance.

Guidance for Clinical Trial Sponsors:
Establishment and Operation of
Clinical Trial Data Monitoring
Committees

OMB Control Number 0910–0581—
Extension

Sponsors are required to monitor
studies evaluating new drugs, biologics,
and devices (21 CFR 312.50 and 312.56
for drugs and biologics and 21 CFR
812.40 and 812.46 for devices). Various
individuals and groups play different
roles in clinical trial monitoring. One
such group is a data monitoring
committee (DMC), appointed by a
sponsor to evaluate the accumulating
outcome data in some trials. A clinical
trial DMC is a group of individuals with
pertinent expertise that reviews on a
regular basis accumulating data from
one or more ongoing clinical trials. The
DMC advises the sponsor regarding the
continuing safety of current trial
subjects and those yet to be recruited to
the trial, as well as the continuing
validity and scientific merit of the trial.

The guidance document referenced in
this document is intended to assist
sponsors of clinical trials in determining
when a DMC is needed for monitoring
a study, and how such committees
should operate. The guidance addresses
the roles, responsibilities, and operating
procedures of DMCs, describes certain
reporting and recordkeeping
responsibilities, including the
following: (1) Sponsor reporting to FDA
on DMC recommendations related to
safety; (2) standard operating
procedures (SOPs) for DMCs; (3) DMC
meeting records; (4) sponsor notification
to the DMC regarding waivers; and (5)
DMC reports based on meeting minutes
to the sponsor.

1. Sponsor Reporting to FDA on DMC
Recommendations Related to Safety

The requirement of the sponsor to
report DMC recommendations related to
serious adverse events in an expedited
manner in clinical trials of new drugs
(21 CFR 312.32(c)) would not apply
when the DMC recommendation is
related to an excess of events not
classifiable as serious. Nevertheless, the
Agency recommends in the guidance
that sponsors inform FDA about all
recommendations related to the safety of
the investigational product whether or
not the adverse event in question meets
the definition of “serious.”

2. SOPs for DMCs

In the guidance, FDA recommends
that sponsors establish procedures to do
the following things:
• Assess potential conflicts of interest
of proposed DMC members;
• Ensure that those with serious
conflicts of interest are not included in
the DMC;
• Provide disclosure to all DMC
members of any potential conflicts that
are not thought to impede objectivity
and, thus, would not preclude service
on the DMC;