and requirements for each clinical trial. The plan should provide those involved in monitoring with adequate information to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring, including those who review and/or determine appropriate action regarding potential issues identified through monitoring, should review the monitoring plan. The components of a monitoring plan are described in the draft guidance, including monitoring plan amendments (i.e., the review and revision of monitoring plans and processes for timely updates). FDA understands that sponsors currently develop monitoring plans; however, not all monitoring plans contain all the elements described in the guidance. Therefore, our following burden estimate provides the additional time that a sponsor would expend in developing a comprehensive monitoring plan based on the recommendations in the guidance. We estimate that approximately 88 sponsors will develop approximately 132 comprehensive monitoring plans in accordance with the draft guidance, and that the added burden for each plan will be approximately 4 hours to develop, including the time needed for preparing monitoring plan amendments when appropriate (a total of 528 hours).

Voluntary Submission of Monitoring Plans to FDA: Section IV.D of the draft guidance permits sponsors to voluntarily and prospectively submit their monitoring plans to the appropriate Center for Drug Evaluation and Research (CDER) review division and request input from the division's clinical trial oversight component (sponsors of significant risk device studies are already required under § 812.25(e) to submit and maintain written procedures for monitoring). We estimate that approximately 22 sponsors will submit approximately 33 monitoring plans to CDER for feedback and that each submission will take approximately 2 hours to complete (a total of 66 hours).

In the **Federal Register** of August 29, 2011 (76 FR 53683), FDA published a 60-day notice requesting public comment on the proposed collection of information. The following is a summary of the comments and FDA's response to the comments for the two collections of information associated with the draft guidance that are not currently approved by OMB.

Development of Comprehensive Monitoring Plan:

FDA received comments that the guidance lacks specific information on development and initialization of risk assessment plans, appropriate mitigation plans, and execution of mitigation plans through the monitoring plan. Addition of use of risk management tools, along with potential applications for using risk-based monitoring strategies would help facilitate implementation.

In response to the comments, FDA included additional detail in the final guidance in an effort to enhance the quality, utility, and clarity of the information collected. Specifically, FDA included additional detail on the development of a monitoring plan, which focuses on the important and likely risks, identified by the risk assessment, to critical data and processes. In addition, FDA included additional guidance on the steps involved in performing a risk assessment and references to tools and methodologies that can be used to perform a risk assessment. FDA clarified that the guidance does not provide comprehensive detail on how to perform a risk assessment.

FDA received several comments that the guidance should specify that it is acceptable for monitoring plans to reference existing standard operating procedures (SOPs) or other documents.

The draft guidance specifies that a monitoring plan may reference existing policies and procedures in order to minimize the burden of the collection of information.

Voluntary Submission of Monitoring Plans to FDA:

FDA received numerous comments that the lack of specific details about FDA review of the monitoring plans early enough in the IND process could delay startup of clinical trials. In addition, numerous comments requested a detailed process or procedure.

Although the draft guidance stated that CDER was considering establishing processes through which sponsors could voluntarily submit monitoring plans for CDER feedback, CDER has concluded that CDER does not have the resources necessary to commit to such a review at this time. CDER is exploring the possibility of a pilot program in this area in the future.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Draft guidance on monitoring clinical investigations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Development of Comprehensive Monitoring Plan	88	1.5	132	4	528

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

Dated: September 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23545 Filed 9–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0938]

Draft Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' FDA is recommending that generic drug manufacturers follow the stability testing recommendations in the International Conference on Harmonisation (ICH) guidances Q1A(R2) through Q1E. The use of these ICH recommendations will standardize FDA's stability testing policies, which will help make the abbreviated new

drug application (ANDA) review process more efficient.

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 December 24, 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Radhika Rajagopalan, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN2, Rm. 243, HFD–640, Rockville, MD 20855, 240–276–8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' Because of increases in numbers of ANDAs and their complexity, the FDA is considering standardizing stability testing policies by adopting recommendations in the following stability related ICH guidances: (1) ''Q1A (R2) Stability Testing of New Drug Substances and Products,'' November 2003; (2) ''Q1B Photostability Testing of New Drug Substances and Products,'' November 1996; (3) ''Q1C Stability Testing for New Dosage Forms,'' November 1996; (4) ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products,'' January 2003; and (5) ''Q1E Evaluation of Stability Data,'' June 2004. FDA is also considering adopting the ICH outlined definitions, glossaries, references, and attachments.

Although the ICH stability guidances were developed for new drug applications to ensure the stability of new drug substances and products, FDA believes the recommendations provided in the ICH guidances on stability testing are appropriate for ANDAs as well. This guidance contains FDA's recommendation that ANDAs submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and the drug master files that support ANDAs, follow the stability recommendations provided in the ICH stability guidances.

This guidance also replaces stability study storage condition recommendations made in an August 18, 1995, letter that the Center for Drug Evaluation and Research's (CDER's) Office of Generic Drugs (OGD) sent to all ANDA applicants, which is available on CDER's Web site: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064995.htm.* The letter stated that OGD would accept ANDAs with the ICH recommended long term room temperature conditions for stability studies, 25 ± 2°C, 60 ± 5 percent RH.

This 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 Agency's current thinking on stability testing of drug substances and products for ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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 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*.

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*.

Dated: September 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23543 Filed 9–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0254 (Formerly Docket No. 2001D–0037)]

Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion'' dated September 2012. The guidance document provides blood establishments with recommendations for pre-storage leukocyte reduction of Whole Blood and blood components intended for transfusion, including recommendations for validation and quality control monitoring of the leukocyte reduction process. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2011 and supersedes the FDA memorandum issued on May 29, 1996, entitled ''Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products.''

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401