label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Richard T. Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4148, Silver Spring, MD 20993–0002, 301–796–1697.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of a revised draft guidance for industry entitled ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.'' This revised draft guidance provides recommendations to applicants on the CMC, human pharmacokinetics and bioavailability, and labeling documentation for liposome drug products submitted in NDAs, ANDAs, and BLAs reviewed by CDER. This revision adds BLAs and ANDAs. It also updates the discussions on liposome technology.

In the **Federal Register** of August 21, 2002 (67 FR 54220), FDA announced the availability of a draft version of this guidance. FDA received comments in response to the draft guidance, and this revised guidance reflects FDA's careful consideration of these comments. Most of the changes to the revised draft guidance were made to clarify statements in the 2002 draft guidance. In addition, FDA decided to publish a revised draft guidance because of changes in technology since the draft was first published in 2002, the addition of BLAs reviewed by CDER as a result of a CDER and Center for Biologics Evaluation and Research reorganization in 2003, and the addition of ANDAs.

The revised draft guidance does not provide recommendations on clinical efficacy and safety studies, nonclinical pharmacology and/or toxicology studies, liposome formulations of vaccine adjuvants or biologics, or drug-lipid complexes.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This revised draft guidance, when finalized, will represent the Agency's current thinking on liposome drug products. 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This revised draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

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

Dated: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27744 Filed 10–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0503]

Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards; Partial Stay and Republication of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of administrative stay of action.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a stay of portions of the final guidance for clinical investigators, sponsors, and institutional review boards (IRBs) entitled ''Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an IND.'' We are republishing the guidance with the portions that are being stayed clearly identified so readers can distinguish parts of the guidance that remain in effect from parts that are subject to this stay.

DATES: This stay is effective October 30, 2015 Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–D–0503 for ''Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards; Partial Stay and Republication of Guidance.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2112, email: *philip.chao@fda.hhs.gov;* or Ebla Ali-Ibrahim, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3691; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 14, 2010 (75 FR 63189), we announced the availability of a draft guidance entitled ''Guidance for Industry: Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies can be Conducted without an IND'' (''the draft guidance''). In the **Federal Register** of September 10, 2013 (78 FR 55262), we published a document announcing the availability of the final version of the guidance, now entitled ''Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards (IRBs) on Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an IND'' (''the final guidance''). We received multiple comments asking for a further opportunity to comment on subsections VI.C and VI.D of the final guidance, which discuss when an IND is needed for studies involving products marketed as cosmetics or foods, respectively. Accordingly, on February 6, 2014, we issued a document reopening the comment period on only those subsections of the final guidance that address the applicability of the IND regulations to clinical research studies involving products marketed as cosmetics or foods (including dietary supplements) (79 FR 7204) (''notice to reopen''). The comment period closed on April 7, 2014. We received comments from trade organizations, individual companies, scientific associations, public interest organizations, and individuals in response to our notice to reopen. These comments raised questions about application of the IND requirement to certain clinical studies of conventional foods, dietary supplements, and cosmetics being investigated for uses covered by the drug definition in section 201(g)(1)(B) or (C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g)(1)(B) or (C)).

II. The Stay

FDA is staying part of the final guidance to allow for further consideration of issues raised by the comments submitted in response to the notice to reopen. Specifically, we are staying portions of subsection VI.D.2, ''Conventional Food,'' and all of subsection VI.D.3, ''Studies Intended to Support a Health Claim,'' except as to studies intended to evaluate whether a food substance reduces the risk of a disease in individuals less than 12 months old, those with altered immune systems, and those with serious or life-threatening medical conditions. Subsections VI.D.2 and VI.D.3 discuss, respectively, conventional food studies generally and studies intended to support a health claim for a conventional food or dietary supplement. The portions of subsection VI.D.2 that are being stayed are the third paragraph (which pertains to clinical studies intended to evaluate a food's effect on the structure or function of the body) and a sentence in the fourth paragraph concerning clinical studies intended to evaluate a non-nutritional effect on the structure or function of the body. In subsection VI.D.3, a text box inserted below the subsection heading explains that clinical investigations intended to evaluate whether a food substance may reduce the risk of a disease in three categories of medically vulnerable subjects (individuals less than 12 months old, those with altered immune systems, and those with serious or life-threatening medical conditions) are excluded from the stay, and that subsection VI.D.3 is in effect for such investigations.

The stay of portions of subsection VI.D.2 and all of subsection VI.D.3 (subject to the exclusion for studies in the medically vulnerable populations described in this document) of the final guidance is effective immediately. All other parts of the final guidance remain in effect. We are republishing the guidance with the stayed material clearly identified so readers can distinguish parts of the guidance that remain in effect from parts that are subject to the stay.

FDA generally does not intend to seek INDs for studies in the stayed categories while the stay is in effect. This stay does not, however, preclude enforcement of any provision of the FD&C Act or other relevant Federal statutes or regulations other than IND requirements (*e.g.,* human subject protection laws and regulations). This stay does not affect investigations of conventional foods or dietary supplements studied for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Products intended for such uses meet the definition of a ''drug'' at section 201(g)(1)(B) of the FD&C Act; such investigations will continue to be subject to IND requirements. For example, dietary supplements containing bacteria have been given to infants born prematurely for prevention of necrotizing enterocolitis. The investigation of such use, and similar uses of conventional foods or dietary supplements to diagnose, cure, mitigate, treat, or prevent a disease, continues to require an IND.

In summary, while the partial stay of the final guidance is in effect, FDA does not consider clinical investigators or study sponsors to be under any

obligation to obtain an IND for the following types of studies evaluating the effects of a product marketed as a conventional food or dietary supplement:

For conventional foods:

• Clinical studies designed to evaluate whether a conventional food may reduce the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions;

• Clinical studies designed to evaluate a non-nutritional effect of a conventional food on the structure or function of the body.

For dietary supplements:

• Clinical studies designed to evaluate whether a dietary supplement may reduce the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.

Further, as noted in the final guidance itself, no IND is required for clinical studies designed to evaluate the nutritional effects of a conventional food, clinical studies designed to evaluate a dietary supplement's effects on the structure or function of the body, or clinical studies designed to evaluate the relationship between a conventional food or dietary supplement and reduced risk of a disease, if there is already an authorized health claim for the substance-disease relationship.

The following types of studies do continue to require an IND for the reasons explained in the final guidance:

For conventional foods:

• Clinical studies designed to evaluate a conventional food's ability to diagnose, cure, mitigate, treat, or prevent a disease, except for studies designed to evaluate whether a conventional food reduces the risk of a disease, intended to support a health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions;

• Clinical studies designed to evaluate whether a food substance reduces the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that includes individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.

For dietary supplements:

• Clinical studies designed to evaluate a dietary supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease, except for studies designed to evaluate whether a dietary supplement reduces the risk of a disease, intended to support a health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions;

• Clinical studies designed to evaluate whether a dietary supplement reduces the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that includes individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.

For cosmetics:

• Clinical studies designed to evaluate a cosmetic's effect on the structure or function of the body or its ability to diagnose, cure, mitigate, treat, or prevent a disease.

Dated: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27729 Filed 10–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3805]

Clinical Trials—Assessing Safety and Efficacy for Diverse Populations; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Johns Hopkins Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop entitled ''Clinical Trials—Assessing Safety and Efficacy in Diverse Populations.'' The purpose of the meeting is to discuss approaches in clinical trial design and subgroup analyses for therapeutic product development and life-cycle management.

DATES: The meeting will be held on December 2, 2015, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3805 for Clinical Trials—Assessing Safety and Efficacy for Diverse Populations; Public Meeting; Request for Comments. Received