

• *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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Mamta Gautam-Basak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 21, Rm. 2508,

Silver Spring, MD 20993, 301–796–0712.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments.” In the absence of availability of a dosage form that is appropriate for the targeted patient population (e.g., pediatric, geriatric), small amounts of liquids and/or soft foods can be used as described in the FDA-approved product labeling for immediate ingestion as the suitable vehicle(s) for oral administration of the specific drug product.

Generally, drug products mixed in small amounts of liquids (5 to 15 milliliters) or soft foods are used in pediatric and other patient populations who are unable to swallow solid oral dosage forms. Liquids and/or soft foods that are shown not to alter performance of the drug product, and are deemed compatible and suitable for use in the targeted patient populations, are considered suitable for use as vehicles with the specific drug product.

This draft guidance addresses the approaches recommended for suitability determination of vehicles intended for use with specific drug products by providing the following:

- Considerations for selection of liquids and/or soft foods as vehicles.
- Standardized in vitro methodology and data recommendations for drug product quality assessments to qualify vehicle(s) for drug product administration.
- Recommendations to communicate acceptable (qualified) vehicles in drug product labeling. If certain foods are found unacceptable, they should also be included in the labeling.

This draft guidance and the methods it describes do not replace existing guidance documents that address food-effect assessments on the drug product or dosage form, or stability testing conducted to support a shelf-life determination. For those drug products marketed with a vehicle for administration (i.e., the vehicle is copackaged with the drug product), the recommendations regarding selection and methods provided in this draft guidance are applicable, but additional considerations and recommendations may also apply.

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 current thinking of FDA on “Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments.” 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 (INDs) have been approved under 0910–0014, the collections of information in 21 CFR part 314 (NDAs and ANDAs) have been approved under 0910–0001, and the collections of information in 21 CFR 201.56 and 201.57 (Prescription Drug Product Labeling) have been approved under 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15870 Filed 7–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Scholarly and Journalistic Activities Deemed Not To Be Research: 2018 Requirements; Draft Guidance; When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 Through January 20, 2019: 2018 Requirements; Draft Guidance Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements; Draft Guidance

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health is announcing the availability of three draft guidance documents titled, “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements,” respectively.

DATES: Submit written comments by August 24, 2018.

ADDRESSES: Submit written requests for single copies of the draft guidance documents titled “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements,” respectively, to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-453-6909. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS-OS-OPHS-2018-0012 (Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements), docket ID number HHS-OS-OPHS-2018-0013 (When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements), and docket ID number HHS-OS-OPHS-2018-0014 (Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements), respectively, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Enter the docket ID number and click on “Search.” On the next page, click the “Comment Now” action and follow the instructions.

- *Mail/Hand Delivery/Courier [For Paper, Disk, or CD-ROM Submissions]:* Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; email Irene.Stith-Coleman@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of three draft guidance documents entitled “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements.” The draft guidance documents, when finalized, will represent OHRP’s current thinking on these topics. OHRP obtained input from HHS agencies and the Common Rule departments and agencies in developing the draft guidance documents.

The “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements” draft guidance explains how certain scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected are deemed not to be research under the 2018 Requirements of the regulations for the protection of human subjects (45 CFR part 46), and consequently do not have to satisfy the requirements of those regulations. It is intended for IRB administrators, IRB chairpersons, relevant institutional officials, and investigators who may be concerned about whether scholarly or journalistic activities need to satisfy the 2018 Requirements of the regulations.

The “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements” draft guidance provides information on the HHS regulations for the protection of human research subjects at 45 CFR part 46 related to the circumstances in which continuing review of research is not required. In particular, this guidance applies to research that transitions to comply with the 2018 Requirements during the 6-month delay period from July 19, 2018 through January 20, 2019. This guidance only applies during the 6-month delay period. It is intended for

Institutional Review Boards (IRBs), investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS.

The “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements” draft guidance provides guidance on the elimination of the requirement in the pre-2018 Requirements (45 CFR 46.103(f)) that each application or proposal for research undergo IRB review and approval as part of the certification process. It is intended for Institutions, IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of nonexempt research involving human subjects conducted or supported by HHS.

II. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP’s website at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>.

Dated: July 19, 2018.

Jerry Menikoff,

Director, Office for Human Research Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is jointly owned by an agency of the U.S. Government with Vanderbilt University, University of Alabama and University of Pennsylvania and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager,