The draft guidance, when finalized, will represent the current thinking of FDA on “Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations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This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of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Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.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]

DEPARTMENT OF HEALTH AND HUMAN SERVICES


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

ACTION: Notice of availability.

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ADDRESSES: Submit written requests for single copies of the draft guidance documents titled “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the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 Assurance, 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 See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance documents.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


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:

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