Articles Containing Active Pharmaceutical Ingredient(s) Considered to be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in section 512(n)(1) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13690 Filed 6–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–N–4066; FDA–2023–N–0918; FDA–2023–N–4259; FDA–2023–N–4849; and FDA–2021–N–0471]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
FDA Recall Regulations	0910–0249	6/30/2027
Food Labeling Regulations	0910–0381	5/31/2027
Export Certificates for FDA Regulated Products	0910–0498	6/30/2027
Food Allergen Labeling and Reporting	0910–0792	6/30/2027
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption—Agricultural Water	0910–0816	6/30/2027

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13638 Filed 6–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0154]

Considerations in Demonstrating Interchangeability With a Reference Product: Update; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product: Update.'' This draft guidance describes considerations regarding a switching study or studies intended to support a demonstration that a proposed therapeutic protein product is interchangeable with a reference product for the purposes of submitting a marketing application or supplement under the Public Health Service Act (PHS Act). After considering any comments received in the docket for this draft guidance, we intend to revise the final guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product'' issued on May 14, 2019, to amend sections in that document regarding the subject addressed in this draft guidance.

DATES: Submit either electronic or written comments on the draft guidance by August 20, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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