



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-9571]

Temporary Policies for Compounding Certain Starter Parenteral Nutrition Drug Products for Neonates; 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 guidance for industry titled “Temporary Policies for Compounding Certain Starter Parenteral Nutrition Drug Products for Neonates.” This guidance describes the FDA’s regulatory and enforcement priorities regarding the compounding of certain starter parenteral nutrition drug products for neonates by outsourcing facilities and by State-licensed pharmacies and Federal facilities that are not registered with FDA as outsourcing facilities. This guidance is being published for immediate implementation due to the expected market exit of the predominant source of certain starter parenteral nutrition drug products for neonates in the United States.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2026-D-9571 for "Temporary Policies for Compounding Certain Starter Parenteral Nutrition Products for Neonates." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

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 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 two self-addressed adhesive labels to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Heather Messick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20903, 240-402-4641.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry, titled “Temporary Policies for Compounding Certain Starter Parenteral Nutrition Drug Products for Neonates.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). This guidance document is being implemented immediately to help ensure patient access to certain starter parenteral nutrition products for neonates, which are essential to the care of this vulnerable patient population. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation.

FDA has determined that temporary enforcement policies for both pharmacy compounders operating under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) and for outsourcing facilities registered under Section 503B of the FD&C Act (21 U.S.C. 353b) are needed to help ensure that treatment options for neonates remain available to hospitals and health systems.

The guidance represents the current thinking of FDA on the “Temporary Policies for Compounding Certain Starter Parenteral Nutrition Drug Products for Neonates.” 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 collections 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 for current good manufacturing practice requirements have been approved under OMB control number 0910-0139. The collections of information for registration of human drug compounding outsourcing facilities under section 503B of the FD&C Act and associated fees under section 744K of the FD&C Act (21 U.S.C. 379j-62) have been approved under OMB control number 0910-0776. The collections of information for human drug compounding and adverse event reporting under sections 503A and 503B (21 U.S.C. 353a and 353b) of the FD&C Act have been approved under OMB control number 0910-0800. The collections of information for adverse product experience reporting under the MedWatch System has been approved under OMB control number 0910-0291.

In addition, the guidance mentions certain records, including records regarding information about which patients received specific compounded products, that FDA expects generally exist as a result of recordkeeping requirements imposed by Federal and State regulatory authorities independent from FDA, including the Centers for Medicare and Medicaid Services and individual State pharmacy licensing authorities. FDA does not believe the guidance includes conducting or sponsoring a collection of information regarding those records.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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