Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0080.

For Policy Related Questions Contact: Effie George at 410–786–8639.

45. Title: Expressions of Interest in the Infant Well-Child Visit Affinity Group

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #72.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0081.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0081.

For Policy Related Questions Contact: Kristin Zycherman at 410–786–6974.

46. Title: Supplemental Payment Reporting Under the Consolidated Appropriations Act, 2021

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #73.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0082.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0082.

For Policy Related Questions Contact: Richard Kimball at 410–786–2278.

47. Title: Coverage of Routine Patient Cost for Items & Services in Qualifying Clinical Trials

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #74.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0083.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0083.

For Policy Related Questions Contact: Myla Adams at 410–786–8107.

48. Title: ARP 1135 State Plan Amendment

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #75.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0084.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0084.

For Policy Related Questions Contact: Kirsten Jensen at 410–786–8146.

49. Title: Expressions of Interest in the Improving Maternal Health by Reducing Low-Risk Cesarean Delivery Affinity Group

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #76.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0085.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0085.

For Policy Related Questions Contact: Richard Kimball at 410–786–2278.

50. Title: COVID–19 Risk Corridor Reconciliation Reporting Template

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #79.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0086.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0086.

For Policy Related Questions Contact: Elizabeth Jones at 410–786–7111.

51. Title: Improving Quality of Care and Outcomes Data for Pregnant Medicaid Beneficiaries and Newborn Infants through Linkage and Evaluation of VR, BC, DC, and TAF

Type of Request: Reinstatement of a previously approved information collection.

CMS ID Number: CMS–10398 #81.

OMB Control Number: 0938–1148.

eRulemaking Docket ID Number: CMS–2024–0172.

Docket Web Address: https://www.regulations.gov/docket/CMS-2024-0172.

For Policy Related Questions Contact: Ali Fokar at 410–786–0020.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–19228 Filed 8–26–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–1131]

Determination That DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (Diltiazem Hydrochloride), 125 Milligrams/125 Milliliters (1 Milligram/Milliliter) and 250 Milligrams/250 Milliliters (1 Milligram/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined that DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem hydrochloride (HCl)), 125 milligrams (mg)/125 milliliters (mL) (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diltiazem HCl, 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Neerja Razdan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, *Neerja.Razdan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA

regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), is the subject of NDA 215252, held by Exela Pharma Sciences, LLC, and initially approved on October 28, 2021. DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% is indicated for the following: (1) temporary control of rapid ventricular rate in atrial fibrillation or atrial flutter; and (2) rapid conversion of paroxysmal supraventricular tachycardias to sinus rhythm.

DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Fresenius Kabi USA, LLC submitted a citizen petition dated March 5, 2024 (Docket No. FDA–2024–P–1131), under 21 CFR 10.30, requesting that the Agency determine whether DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3925]

Authorization of Emergency Use of a Freeze-Dried Plasma Product for Treatment of Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use of a freeze-dried plasma product, octaplasLG Powder, for emergent treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

DATES: The Authorization is effective as of August 8, 2024.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), 21st Century Cures Act (Pub. L. 114–255), and Public Law 115–92 (2017), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents and other agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces. Among other actions, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents and other agents that may cause, or are otherwise associated with, an imminently life-threatening