determined that LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 milligrams (mg)/0.5 milliliter (mL) estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for estradiol cypionate and medroxyprogesterone acetate injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Grace St.Vincent, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6215, Silver Spring, MD 20993–0002, 240–402–9201, *Grace.StVincent@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, is the subject of NDA 020874, held by Pharmacia and Upjohn Co., and initially approved on October 5, 2000. LUNELLE is indicated for the prevention of pregnancy.

In a letter dated June 24, 2003, Pharmacia and Upjohn Co. requested withdrawal of NDA 020874 for LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of NDA 020874, effective June 4, 2004.

Sarah A. Norring, Ph.D. submitted a citizen petition dated June 20, 2024 (Docket No. FDA–2024–P–2952), under 21 CFR 10.30, requesting that the Agency determine whether LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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 LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, was not withdrawn for reasons of safety or effectiveness. The petitioner provided information about a voluntary recall of prefilled syringes of LUNELLE in October 2002 due to potential manufacturing issues at a particular facility. We have carefully reviewed our files for records concerning the withdrawal of LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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 LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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. ANDAs that refer to LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, may 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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22680 Filed 12–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4734]

Determination That DEMEROL (Meperidine Hydrochloride) Tablet, 100 Milligrams, and Other Drug Products Were 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 Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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 (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in table 1 are no longer being marketed.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 005010	DEMEROL	Meperidine Hydrochloride	100 Milligrams (mg)	Tablet; Oral	Quagen Pharmaceuticals LLC.
NDA 009402	DELESTROGEN	Estradiol Valerate	40 mg/Milliliter (mL)	Injectable; Injection	Endo Operations Ltd.
NDA 011338	FLUOTHANE	Halothane	99.99%	Liquid; Inhalation	Wyeth-Ayerst Laboratories.
NDA 017354	LOESTRIN FE 1/20	Ethinyl Estradiol, Norethindrone Acetate.	0.02 mg, 1 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D Inc.
NDA 018063	CORGARD	Nadolol	20 mg; 40 mg; 80 mg	Tablet; Oral	US WorldMeds, LLC.
NDA 019429	FIORINAL W/CODEINE	Aspirin, Butalbital, Caffeine, Codeine Phosphate.	325 mg, 50mg, 40 mg, 30mg	Capsule; Oral	Allergan.
NDA 019758	CLOZARIL	Clozapine	50 mg; 200 mg	Tablet; Oral	Heritage Life Sciences Barbados Inc.
NDA 020496	AMARYL	Glimepiride	1 mg; 2 mg; 4 mg	Tablet; Oral	Sanofi-Aventis U.S. LLC.
NDA 020768	ZOMIG	Zolmitriptan	2.5 mg; 5 mg	Tablet; Oral	IPR Pharmaceuticals, Inc.
NDA 020933	VIRAMUNE	Nevirapine	50 mg/5 mL	Suspension; Oral	Boehringer Ingelheim Pharmaceuticals Inc.
NDA 021123	ULTRACET	Acetaminophen, Tramadol Hydrochloride.	325 mg, 37.5 mg	Tablet; Oral	Janssen Pharmaceuticals Inc.
NDA 021142	OLUX	Clobetasol Propionate	0.05%	Aerosol, Foam; Topical	Norvium Bioscience, LLC.
NDA 021231	ZOMIG–ZMT	Zolmitriptan	2.5 mg; 5 mg	Orally Disintegrating Tablet; Oral.	AstraZeneca Pharmaceuticals LP.
NDA 021368	CIALIS	Tadalafil	2.5 mg	Tablet; Oral	Eli Lilly and Co.
NDA 021497	ALINIA	Nitazoxanide	500 mg	Tablet; Oral	Romark Laboratories.
NDA 021636	ZEGERID	Omeprazole, Sodium Bicarbonate.	20 mg/Packet, 1.68 grams (g)/Packet; 40 mg/Packet, 1.68 g/Packet.	For Suspension; Oral	Salix Pharmaceuticals Inc.
NDA 021689	NEXIUM IV	Esomeprazole Sodium	EQ 40 mg Base/Vial	Injectable; Intravenous	AstraZeneca Pharmaceuticals LP.
NDA 021799	QUALAQUIN	Quinine Sulfate	324 mg	Capsule; Oral	Sun Pharmaceutical Industries, Inc.
NDA 021937	ATRIPLA	Efavirenz, Emtricitabine, Tenofovir Disoproxil Fumarate.	600 mg, 200 mg, 300 mg	Tablet; Oral	Gilead Sciences, Inc.
NDA 021963	ALLEGRA	Fexofenadine Hydrochloride.	30 mg/5 mL	Suspension; Oral	Chattem Inc., DBA Sanofi Consumer Healthcare.
NDA 022331	KAPVAY	Clonidine Hydrochloride	0.1 mg	Extended-Release Tablet; Oral.	Concordia Pharmaceuticals, Inc.
NDA 022352	COLCRYS	Colchicine	0.6 mg	Tablet; Oral	Takeda Pharmaceuticals USA, Inc.
NDA 050682	COSMEGEN	Dactinomycin	0.5 mg/Vial	Injectable; Injection	Recordati Rare Diseases Inc.
NDA 050717	MONUROL	Fosfomycin Tromethamine.	EQ 3 g Base/Packet	For Solution; Oral	Zambon Company S.p.A.
ANDA 086162	BUTALBITAL, ASPIRIN AND CAFFEINE.	Aspirin, Butalbital, Caffeine.	325 mg, 50 mg, 40 mg	Tablet; Oral	Hikma International Pharmaceuticals LLC.
ANDA 087056	CYPROHEPTADINE HYDROCHLORIDE.	Cyproheptadine Hydrochloride.	4 mg	Tablet; Oral	Avet Pharmaceuticals.
ANDA 088763	PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE.	Codeine Phosphate, Promethazine Hydrochloride.	10mg/5mL, 6.25mg/5mL	Syrup; Oral	Actavis Mid-Atlantic, LLC.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22681 Filed 12–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Model Eligibility Review Survey, OMB No. 0906–XXXX—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 12, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review Survey, OMB No. 0915–XXXX—New.

Abstract: HRSA's MIECHV Program supports voluntary, evidence-based home visiting services for expectant and new parents with young children up to kindergarten entry living in at-risk communities. The MIECHV Program was last reauthorized in December 2022.[1] One key program requirement is that programs deliver services using models that meet HHS criteria for evidence of effectiveness, referred to as evidence-based models.[2] The Administration for Children and Families administers the Home Visiting Evidence of Effectiveness (HomVEE) review process to identify early childhood home visiting models that demonstrate evidence of effectiveness.[3] However, not all evidence-based service delivery models approved through the HomVEE process meet MIECHV statutory requirements as enacted in the last reauthorization of the program in 2022 such that they may be used to carry out the MIECHV Program in fidelity to applicable program requirements.

In 2021, HRSA issued a Request for Information notice and request for comment regarding its proposal to standardize criteria for assessing model eligibility to be implemented using MIECHV Program funds.[4] This 2025 ICR reflects new MIECHV statutory provisions that were added in December 2022 and thus replaces that 2021 notice. HRSA is issuing this ICR to propose a survey to identify service delivery models that meet both HHS criteria for evidence of effectiveness, as determined by HomVEE review, and applicable MIECHV statutory requirements, and therefore may be used by funding recipients to provide home visiting services through the MIECHV Program. This will be accomplished by validating whether evidence-based models, as determined by HomVEE, align with the MIECHV Program's statutory requirements, as further discussed in this notice. This process will ensure that models used by funding recipients (and their local implementing agencies) to deliver MIECHV Program services effectively meet core components of the MIECHV Program, including those added during the program's 2022 reauthorization.

Following approval of this ICR request, HRSA will begin the process of assessing all models that meet HHS criteria for evidence of effectiveness, as determined by the HomVEE review, to determine their MIECHV eligibility. It will initiate this process by requesting information from home visiting model developers through a standardized survey. As of November 2025, HomVEE lists 24 models that meet HHS criteria for evidence of effectiveness.[5] Upon receiving the survey from HRSA, model developers will have 30 days to provide requested information on model characteristics, resources, and processes. A panel of HRSA reviewers will assess the survey responses against the MIECHV statutory requirements. Any of the 24 evidence-based models that also meet these statutory criteria will be considered eligible for MIECHV Program implementation and remain eligible for implementation after the end of the current performance period. Models that do not meet these criteria will be deemed ineligible for use by funding recipients (and their local implementing agencies) to carry out the MIECHV Program and may continue to be used only through the currently applicable period of performance. HRSA will work with funding recipients regarding any changes in model approval that may affect their program implementation; however, funding

[1] Section 6101 of the Consolidated Appropriations Act, 2023, Public Law 117–328, recently amended Section 511 of the Social Security Act, as added by the Patient Protection and Affordable Care Act, Public Law 111–148, Section 2951, and extended appropriated funding through fiscal year 2027.

[2] 42 U.S.C. 711(d)(3)(C)(i).

[3] The current HHS criteria for evidence-based models can be found at: *https://homvee.acf.hhs.gov/about-us/hhs-criteria.*

[4] HRSA, HHS. ''Statutory Requirements and Process Standardization: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review.'' **Federal Register** 86, no. 184 (September 27, 2021): 53329. *https://www.federalregister.gov/d/2021-20853.*

[5] HomVEE lists home visiting models that meet HHS criteria for evidence of effectiveness at: *https://homvee.acf.hhs.gov/HRSA-Models-Eligible-MIECHV-Grantees.*