

sole instrument implemented for this purpose. *Form Number:* CMS-8550 (OMB control number 0938-1135); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits), State, Local, or Tribal Governments; *Number of Respondents:* 2,250; *Number of Responses:* 2,250; *Total Annual Hours:* 1,125. (For policy questions regarding this collection contact Frank Whelan at 410-786-1302).

### 3. *Type of Information Collection*

*Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* Section 6409 of the ACA requires the Secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. The SRDP is a voluntary self-disclosure process that allows providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. For purposes of the SRDP, a person submitting a disclosure to the SRDP will be referred to as a “disclosing party.” CMS analyzes the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition.

Specifically, under the proposal a physician practice disclosing group practice noncompliance will submit an SRDP form consisting of the following components: (1) the SRDP Disclosure Form, (2) a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals to the practice, and (3) a Financial Analysis Worksheet. All other entities will continue to submit disclosures using the SRDP Disclosure Form, separate Physician Information Forms for each physician covered in the self-disclosure, and a Financial Analysis Worksheet. *Form Number:* CMS-10328 (OMB control number: 0938-1106); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 4,950. (For policy questions regarding this collection contact Caitlin Bailey at 410-786-9768.)

### 4. *Type of Information Collection*

*Request:* Revision of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The Secretary of Health and Human Services (HHS), hereafter known as “The Secretary,” codified 45 CFR parts

160 and 164 Administrative Simplification provisions that apply to the enforcement of the Health Insurance Portability and Accountability Act of 1996 Public Law 104-191 (HIPAA). The provisions address rules relating to the investigation of non-compliance of the HIPAA Administrative Simplification code sets, unique identifiers, operating rules, and transactions. 45 CFR 160.306, Complaints to the Secretary, provides for investigations of covered entities by the Secretary. Further, it outlines the procedures and requirements for filing a complaint against a covered entity.

Anyone can file a complaint if he or she suspects a potential violation. Persons believing that a covered entity is not utilizing the adopted Administrative Simplification provisions of HIPAA are voluntarily requested to file a complaint with CMS via the Administrative Simplification Enforcement and Testing Tool (ASETT) online system, by mail, or by sending an email to the HIPAA mailbox at [hipaacomplaint@cms.hhs.gov](mailto:hipaacomplaint@cms.hhs.gov). Information provided on the standard form will be used during the investigation process to validate non-compliance of HIPAA Administrative Simplification provisions.

This standard form collects identifying and contact information of the complainant, as well as the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS’ findings. *Form Number:* CMS-10148 (OMB control number: 0938-0948); *Frequency:* Occasionally; *Affected Public:* Private sector, Business or Not-for-profit institutions, State, Local, or Tribal Governments, Federal Government, Not-for-profits institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Kevin Stewart at 410-786-6149).

### 5. *Type of Information Collection*

*Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Transparency in Coverage Reporting by Qualified Health Plan Issuers; *Use:* Sections 1311(e)(3)(A)-(C) of the ACA, as implemented at 45 CFR 155.1040(a)-(c) and 156.220, establish standards for qualified health plan (QHP) issuers to submit specific information related to transparency in coverage. QHP issuers are required to post and make data related to transparency in coverage available to the public in plain language and submit this data to the Department

of Health and Human Services (HHS), the Exchange, and the state insurance commissioner. Section 2715A of the Public Health Service (PHS) Act as added by the ACA largely extends the transparency provisions set forth in section 1311(e)(3) to non-grandfathered group health plans and health insurance issuers offering group and individual health insurance coverage. *Form Number:* CMS-10572 (OMB control number: 0938-1310); *Frequency:* Annually; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 400; *Number of Responses:* 400; *Total Annual Hours:* 22,000. (For questions regarding this collection, contact Jack Reeves at 301-492-5152.)

**William N. Parham, III,**

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

[FR Doc. 2025-18506 Filed 9-23-25; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[FDA-2025-N-3346]

#### Elite Laboratories, Inc., et al.; Withdrawal of Approval of 72 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 72 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of October 23, 2025.

#### FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-3471, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing.

Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 040228 .....	Phentermine Hydrochloride (HCl) capsule, 37.5 milligrams (mg)	Elite Laboratories, Inc., 165/144/135 Ludlow Ave., Northvale, NJ 07647.
ANDA 040538 .....	Prednisone tablet, 2.5 mg .....	Hikma Pharmaceuticals USA Inc., U.S. Agent for Hikma Pharmaceuticals LLC, 1809 Wilson Rd., Columbus, OH 43228.
ANDA 040890 .....	Prednisone tablet, 1 mg .....	Do.
ANDA 063000 .....	Polymyxin B Sulfate injectable, Equivalent to (EQ) 500,000 units base/vial.	Adrastea Pharma LLC, 1008 S Main St., Suite 225, Georgetown, TX 78626.
ANDA 065175 .....	Nystatin powder, 100,000 units/gram (gm) .....	Do.
ANDA 065177 .....	Colistimethate Sodium injectable, EQ 150 mg base/vial .....	Nexus Pharmaceuticals, LLC, 400 Knightsbridge Parkway, Lincolnshire, IL 60069.
ANDA 065455 .....	Vancomycin HCl injectable, EQ 10 gm base/vial .....	Hospira, Inc., 275 North Field Dr., Building H1-3S, Lake Forest, IL 60045.
ANDA 065511 .....	Azithromycin injectable, EQ 500 mg base/vial .....	Do.
ANDA 070631 .....	Valproic Acid capsule, 250 mg .....	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 071425 .....	DESOWEN (desonide) ointment, 0.05% .....	Galderma Laboratories, L.P., 2001 Ross Ave., Suite 1600, Dallas, TX 75201.
ANDA 072354 .....	DESOWEN (desonide) ointment, 0.05% .....	Do.
ANDA 072786 .....	Fentanyl Citrate injectable, EQ 0.05 mg base/milliliter (mL) .....	Hospira, Inc.
ANDA 073045 .....	Albuterol aerosol, metered, 0.9 mg/inhalation .....	Mylan Pharmaceuticals ULC (formerly Genpharm Inc.), 781 Chestnut Ridge Rd., Morgantown, WV 26505.
ANDA 074332 .....	Bumetanide injectable, 0.25 mg/mL .....	Hospira, Inc.
ANDA 074776 .....	Timolol Maleate solution, EQ 0.5% base .....	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 074778 .....	Timolol Maleate solution, EQ 0.25% base .....	Do.
ANDA 074912 .....	Selegiline HCl tablet, 5 mg .....	Stason Pharmaceuticals, Inc., U.S. Agent for Kenton Chemicals and Pharmaceuticals Corp., 11 Morgan, Irvine, CA 92618.
ANDA 074941 .....	Diltiazem HCl injectable, 5 mg/mL .....	Hospira, Inc.
ANDA 074993 .....	Ketorolac Tromethamine injectable, 30 mg/mL, and 15 mg/mL ..	Do.
ANDA 075505 .....	Loratadine syrup, 1 mg/mL .....	Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 075940 .....	Dacarbazine injectable, 200 mg/vial .....	Hospira, Inc.
ANDA 075962 .....	Tramadol HCl tablet, 50 mg .....	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 076715 .....	Modafinil tablets, 100 mg, and 200 mg .....	Do.
ANDA 076774 .....	Haloperidol injectable, EQ 5 mg base/mL .....	Syneos Health, LLC, U.S. Agent for Gland Pharma Limited, 1030 Sync St., Morrisville, NC 27560.
ANDA 078024 .....	Ciprofloxacin in Dextrose, injectable, 5% in plastic container, 200 mg/100 mL, and 400 mg/200 mL.	Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015.
ANDA 078030 .....	Stavudine for solution, 1 mg/mL .....	Cipla USA, Inc., U.S. Agent for Cipla Limited, 10 Independence Blvd., Suite 300, Warren, NJ 07059.
ANDA 078062 .....	Ciprofloxacin injectable, 200 mg/20 mL (10 mg/mL), and 400 mg/40mL (10 mg/mL).	Baxter Healthcare Corp.
ANDA 078084 .....	Metronidazole in plastic container, injectable, 500 mg/100 mL ...	Do.
ANDA 078095 .....	Zaleplon capsules, 5 mg, and 10 mg .....	Upsher-Smith Laboratories, LLC.
ANDA 078213 .....	Propranolol HCl tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg.	NorthStar Rx LLC, U.S. Agent for NorthStar Healthcare Holdings Limited, 4835 Crumpler Rd., Suite A, Memphis, TN 38141.
ANDA 078253 .....	Allopurinol tablets, 100 mg, and 300 mg .....	Do.
ANDA 079211 .....	Ranitidine HCl syrup, EQ 15 mg base/mL .....	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC, U.S. Agent for Wockhardt Limited, 6451 Main St., Morton Grove, IL 60053.
ANDA 079212 .....	Ranitidine HCl syrup, EQ 15 mg base/mL .....	Do.
ANDA 084399 .....	Phendimetrazine Tartrate tablet, 35 mg .....	Upsher-Smith Laboratories, LLC.
ANDA 088465 .....	Prednisone tablet, 50 mg .....	Hikma Pharmaceuticals USA Inc., U.S. Agent for Hikma Pharmaceuticals LLC.
ANDA 089804 .....	Fluphenazine HCl tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg .....	Prasco, LLC dba Prasco Laboratories, 6125 Commerce Ct., Mason, OH 45040.
ANDA 090071 .....	Venlafaxine HCl extended-release capsules, EQ 37.5 mg base, EQ 75 mg base, and EQ 150 mg base.	Bausch Health US LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 090075 .....	Epirubicin HCl injectable, 50 mg/25 mL (2 mg/mL), and 200 mg/100 mL (2 mg/mL).	Hisun Pharmaceuticals USA, Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd., 200 Crossing Blvd., 2nd floor, Bridgewater, NJ 08807.
ANDA 090125 .....	Nicardipine HCl injectable, 25 mg/10 mL (2.5 mg/mL) .....	Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618.
ANDA 090811 .....	Bivalirudin injectable, 250 mg/vial .....	Hospira, Inc.
ANDA 091095 .....	Nitrofurantoin capsules, 25 mg, 50 mg, and 100 mg .....	Actavis Laboratories FL, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 091152 .....	Benzotropine Mesylate injectable, 1 mg/mL .....	Luitpold Pharmaceuticals, Inc., One Luitpold Dr., P.O. Box 9001, Shirley, NY 11967.
ANDA 091397 .....	Levofloxacin injectable, EQ 250 mg/50 mL (EQ 5 mg/mL), EQ 750 mg/150 mL (EQ 5 mg/mL), and EQ 500 mg/100 mL (EQ 5 mg/mL).	Baxter Healthcare Corp.
ANDA 091596 .....	Tranexamic Acid injectable, 100 mg/mL .....	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 091667 .....	Misoprostol tablets, 0.1 mg, and 0.2 mg .....	Novel Laboratories Inc., 400 Campus Dr., Somerset, NJ 08873.
ANDA 091671 .....	Hydrocodone Polistirex and Chlorpheniramine Polistirex extended-release suspension, EQ 8 mg maleate/5 mL; EQ 10 mg bitartrate/5 mL.	Neos Therapeutics, LP, 2940 N Highway 360, Suite 400, Grand Prairie, TX 75050.
ANDA 201634 .....	Donepezil HCl tablets, 5 mg, and 10 mg .....	Indicus Pharma LLC, 2530 Meridian Parkway, Suite 300, Durham, NC 27713.
ANDA 203106 .....	Potassium Chloride extended-release capsules, 8 milliequivalent (mEq) and, 10 mEq.	Upsher-Smith Laboratories, LLC.
ANDA 203110 .....	Hydralazine HCl injectable, 20 mg/mL .....	Adrastea Pharma LLC.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 203665 .....	Fludeoxyglucose F18 injectable, 20–500 millicurie (mCi)/mL .....	SOFIE Co. dba SOFIE, 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166.
ANDA 204403 .....	Rivastigmine extended-release film, 4.6 mg/24 hours (hr), 9.5 mg/24 hr, and 13.3 mg/24 hr.	Alvogen, Inc., 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 204530 .....	Sodium Fluoride F18 injectable, 10–200 mCi/mL .....	B&H Consulting Services, Inc., U.S. Agent for Hot Shots NM, LLC, 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 204541 .....	Sodium Fluoride F18 injectable, 10–200 mCi/mL .....	Essential Isotopes LLC, 1513 Research Park Dr., Columbia, MO 65211.
ANDA 204667 .....	Ammonia N 13 injectable, 18.8 mCi-188 mCi/5 mL (3.75–37.5 mCi/mL).	SOFIE Co. dba SOFIE.
ANDA 204860 .....	Prochlorperazine Edisylate injectable, EQ 5 mg base/mL .....	Nexus Pharmaceuticals, LLC.
ANDA 205901 .....	Telmisartan tablets, 20 mg, 40 mg, and 80 mg .....	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd., Unit V, 1035 Centennial Ave., Piscataway, NJ 08854.
ANDA 206071 .....	Methocarbamol solution, 1 gram (gm)/10 mL (100 mg/mL) .....	Navinta LLC.
ANDA 206468 .....	Dicyclomine HCl injectable, 10 mg/mL .....	Nexus Pharmaceuticals, LLC.
ANDA 206561 .....	Indomethacin Sodium injectable, EQ 1 mg base/vial .....	Navinta LLC.
ANDA 206681 .....	Oxacillin Sodium injectable, EQ 1 gm base/vial, and EQ 2 gm base/vial.	Piramal Critical Care, Inc., 3950 Schelden Circle, Bethlehem, PA 18017.
ANDA 206724 .....	Budesonide delayed-release capsule, 3 mg .....	Syneos Health, LLC, U.S. Agent for Natco Pharma Limited, 1030 Sync St., Morrisville, NC 27560.
ANDA 206760 .....	Oxacillin Sodium injectable, EQ 10 gm base/vial .....	Piramal Critical Care, Inc.
ANDA 208679 .....	Fludeoxyglucose F 18 injectable, 20–300 mCi/mL .....	Memorial Sloan Kettering Cancer Center, 1275 York Ave., New York, NY 10065.
ANDA 208878 .....	Midazolam HCl injectable, EQ 5 mg base/mL .....	Fresenius Kabi USA, LLC.
ANDA 210356 .....	Haloperidol injectable, EQ 5 mg base/mL .....	Do.
ANDA–210774 .....	Acyclovir ointment, 5% .....	Apotex Corp., U.S. Agent for Apotex Inc., 2400 North Commerce Pkwy., Suite 400, Weston, FL 33326.
ANDA 211794 .....	Acyclovir ointment, 5% .....	Cipla USA, Inc., U.S. Agent for Cipla Limited.
ANDA 212775 .....	Azelastine HCl spray, metered, 0.2055 mg/spray .....	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 213247 .....	Metformin HCl extended-release tablets, 500 mg, and 1 gm .....	Elity, LLC, U.S. Agent for TWI Pharmaceuticals, Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027.
ANDA 213394 .....	Metformin HCl extended-release tablets, 500 mg, and 1 gm .....	PHL US Pharma LLC, U.S. Agent for Utopic Pharmaceuticals Inc., 3396 Kipling St., Palo Alto, CA 94306.
ANDA 213823 .....	Bortezomib injectable, 3.5 mg/vial .....	Baxter Healthcare Corp.
ANDA 214436 .....	Pemetrexed Disodium powder, EQ 100 mg base/vial, and EQ 500 mg base/vial.	Do.
ANDA 218354 .....	Edaravone solution, 30 mg/100 mL (0.3 mg/mL) .....	Long Grove Pharmaceuticals LLC, 9450 W Bryn Mawr Ave., Suite 200, Rosemont, IL 60018.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of October 23, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on October 23, 2025 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

**Grace R. Graham,**  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.

[FR Doc. 2025–18453 Filed 9–23–25; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2025–N–3959]

**Approval of Previously Withdrawn New Drug Application for WELLCOVORIN (Leucovorin Calcium) Tablets**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing approval of the previously withdrawn new drug application (NDA) for Wellcovorin (leucovorin calcium) tablets, equivalent to (EQ) 5 milligrams (mg) base and EQ 25 mg base. FDA is initiating this action on the basis of new data and is required to publish notice of approval of an NDA for which the Agency had previously withdrawn approval.

**FOR FURTHER INFORMATION CONTACT:** Harold Sano, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4355, Silver Spring, MD 20993–0002, 301–796–2429, [Harold.Sano@fda.hhs.gov](mailto:Harold.Sano@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing approval of the previously withdrawn NDA 018342 for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base in accordance with 21 CFR 314.160, which provides, in relevant part, that FDA may, on the basis of new data, approve an application for which it had previously withdrawn approval.

Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, are the subject of NDA 018342, initially approved on July 8, 1983, and held by GlaxoSmithKline (GSK). The most recently approved labeling for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, stated that the drug products were indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdoses of folic acid antagonists. In the **Federal Register** of September 22, 1999, FDA announced that it was withdrawing approval of NDA 018342 after GSK notified the Agency that Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, were no longer marketed and requested that the approval of the application be withdrawn under 21 CFR 314.150(c). Subsequently, in the **Federal**