enrolled suppliers when they are reporting a change in their ownership, a change in their current Medicare enrollment information, or are revalidating or reactivating their Medicare enrollment. *Form Number:* CMS–855B (OMB control number: 0938–1377); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 132,800; *Number of Responses:* 132,800; *Total Annual Hours:* 155,884. (For questions regarding this collection, contact Frank Whalen at 410–786–1302 or *Frank.Whelan@cms.hhs.gov.*)

William N. Parham, III,

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

[FR Doc. 2025–00696 Filed 1–14–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0168]

Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to reduce the opiate alkaloid content of poppy seeds. We are taking this action, in part, because we have received reports of adverse events related to the use of some poppy seed products. We intend to use the information to help determine what type(s) of actions, if any, we should take to help ensure that poppy seed products do not pose a health risk when consumed.

DATES: Either electronic or written comments on the notice must be submitted by April 15, 2025.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2021–P–0168 for ''Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices related to Opiate Alkaloids; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: Jesse Lunzer, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2879, or Holli Kubicki, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to reduce the opiate alkaloid content of poppy seeds. The opium poppy (*Papaver somniferum*), or the ''poppy plant,'' is cultivated for food use, decorative use, ornamental use, and

medicinal purposes. In the poppy plant, seeds grow inside an enclosed round fruit that is often referred to as a ''capsule'' or ''seed capsule.'' The poppy plant produces substances, including alkaloids, to maintain the biological processes needed to grow and reproduce. Morphine, codeine, and thebaine are alkaloids produced by poppy plants and are referred to as opiate alkaloids.

The scientific literature and FDA's preliminary surveillance sampling show that poppy seeds may have varying amounts of opiate alkaloids and that opiate alkaloids may be present on poppy seeds or in poppy seed-containing foods. Opiate alkaloid exposure may cause a range of side effects, including unusual dizziness or lightheadedness, sedation, extreme sleepiness, slowed or difficult breathing, unresponsiveness, respiratory arrest, and, in some cases, death. Reports of adverse events associated with poppy seed consumption have also garnered concern among citizens and consumer groups such as the Center for Science in the Public Interest (Ref. 1).

FDA is aware that some consumers have used poppy seeds to produce a ''poppy seed tea'' that has been linked to serious adverse events, including death. ''Tea'' is a misnomer, as the beverage is a solution that results from rinsing the opiate alkaloid-containing latex residue from the outer hull of the poppy seeds using cold water, and not an infusion created by steeping the seeds in hot water. To date, FDA has received nine reports of deaths purportedly associated with the consumption of homemade poppy seed tea. The cause of death for eight cases was morphine intoxication, often with codeine from poppy seeds and other substances (prescription opioids, benzodiazepines, anticonvulsants, mitragynine (kratom), and cannabis) also involved.

FDA's efforts to expand our understanding of opiate alkaloids on poppy seeds and consumer behaviors related to poppy seed consumption include surveillance sampling and testing poppy seeds from marketed products to determine their opiate alkaloid content. Twenty-one samples taken from poppy seeds purchased online showed morphine levels between 1 milligram per kilogram (mg/kg) and 520 mg/kg (median 70 mg/kg; mean 120.4 mg/kg) and codeine levels between 0.8 mg/kg and 255 mg/kg (median 85 mg/kg; mean 113.1 mg/kg). We also have been examining agricultural and manufacturing practices related to poppy seeds and are interested in learning whether there are agricultural or manufacturing practices that might reduce the presence of the opiate alkaloids on poppy seeds.

Our current understanding is that most opiate alkaloids on poppy seeds are deposited on the seeds by means of contact with liquid or dried latex that may occur through pod/capsule damage and/or particulate latex-derived dust through growing, harvesting, and processing practices (Refs. 2–4). Because these practices may vary depending on the grower or manufacturer and the intended use of the poppy plant (*e.g.,* whether it is grown for food or pharmaceutical purposes), we would like more detailed information about the specific practices and processes from growth of the poppy plant and harvesting of poppy seeds to the processing and manufacturing of poppy seeds and poppy seed food products in the marketplace.

Accordingly, we are seeking additional information on industry practices, such as information about the poppy seed supply chain and harvesting, handling, and testing practices, as well as manufacturing, processing, or other practices available and in use by industry to reduce or otherwise affect the opiate alkaloid content of poppy seeds. This information would help FDA understand existing industry practices and determine what type(s) of actions, if any, we should take to help to ensure that poppy seed products do not pose a health risk when consumed.

II. Issues for Consideration and Request for Information

We invite comment in response to the questions below. Please explain your answers and provide references and data, if possible. Including contextual information about your role(s) in the poppy seed industry (*e.g.,* grower, importer, retailer) would also be helpful.

A. Questions About Growing, Harvesting, and Post-Harvest Processes of Poppy Plant Crops and Poppy Seeds

As background, a poppy plant's production of opiate alkaloids varies based on certain environmental, biological, and inter-cultivar genetic variation. In addition, we are aware that agricultural practices that occur during poppy plant growth may impact opportunities for opiate alkaloid-containing latex to be deposited on seeds (Refs. 2–5 and 9).

Dried mature poppy plants are commonly harvested by using mechanized harvesting machinery that cuts and removes the above-ground plants after the plants have died and dried out in the field (Refs. 6–9). We want to learn about the types of harvesting practices and machinery used, because harvesting dried plants can result in the production of opiate alkaloid-containing dust or particulate plant tissue that may be deposited on the seeds (Ref. 9).

We also are aware of some practices that are used to separate seeds from the seed capsules. For example, firms might use threshing machines, which crush the capsules and release the seeds. Other practices involve use of sieves, gravity tables, or other cleaning machines intended to separate the seeds from debris (such as small fragments of capsules, stems, or rocks) by shaking or blowing air through a permeable surface and separating plant material by size (Ref. 8). Opiate alkaloids might be transferred to the outer surface of poppy seeds during various harvesting and post-harvesting steps.

Question 1: Please tell us about the growing, harvesting, and post-harvest processes used to produce poppy plant crops and seeds and what types of equipment are used for these processes. What, if any, are the different processes used for different geographic areas where the plant(s) are grown and why are the different processes used? We are particularly interested in information about good agricultural practices, scoring or nicking pods, harvesting procedures, cleaning and separation of plant parts, opiate alkaloid testing method and frequency, thermal treatments (*e.g.,* to degrade opiate alkaloids), packaging, cleaning of equipment, frequency of cleaning, and storage.

Question 2: Do buyers of poppy plants request specific varieties or cultivars based on the amount of opiate alkaloid produced by the variety or cultivar? If so, what are the specific varieties or cultivars and, if known, what are the preferred uses for these varieties or cultivars, and why are those varieties or cultivars preferred?

Question 3: What types of equipment (*e.g.,* agricultural threshers, combines, cultivators, other equipment) are used for harvesting poppy plants? FDA is aware that machine harvesting can result in opiate alkaloids being deposited on poppy seeds (Ref. 9). Please elaborate on style, model, settings, etc.

Question 4: What practices are used to monitor, control, reduce, or otherwise affect poppy seed opiate alkaloid content, such as opiate alkaloid testing or poppy seed heat treatments (Refs. 10–12)? We are particularly interested in information on the types of practices to reduce opiate alkaloids and frequency of

use of the practices, as well as any evidence of their impact on the opiate alkaloid content of poppy seeds and the quality of the seeds.

B. Questions About Poppy Seed Supply Chain

We also seek information about distribution chains of poppy seeds and activities conducted during distribution (for example, opioid alkaloid testing and poppy seed heat treatment). Poppy seeds might be sourced from poppy plants that are grown solely for food use. In addition, seeds from poppy plants that are grown for pharmaceutical purposes might be sold for human food consumption (Refs. 4 and 6). Thus, FDA also wants to better understand the practices of companies that sell poppy capsules and seeds from plants grown for pharmaceutical purposes to entities involved in food manufacturing and distribution, at all points in time from the growth of poppy plants to the sale of poppy seeds. Cultivars grown for pharmaceutical purposes may produce higher opiate alkaloids compared to cultivars grown solely for food use, which may result in higher opiate alkaloid content on seeds. These cultivars and their seeds might be more affected by the practices involved in growing, harvesting, processing, and distribution.

Question 5: What are the various intermediaries and processes that are part of the supply chain for poppy seeds? Please include information about what intermediaries (such as brokers, exporters, importers, consolidators, manufacturers, and retailers) and processes (such as opiate alkaloid testing, testing frequency, packing, sale, and transportation) might be involved at various stages throughout the poppy seed supply chain.

Question 6: What activities are performed in the distribution chains of poppy seeds? For example, do distributors or wholesalers engage in opioid alkaloid testing and heat treatments of poppy seeds? If so, what types of testing, treatments, or other activities are performed and how frequently are such activities performed?

Question 7: Describe the role of any brokers or other intermediary distributors that sell poppy seeds between pharmaceutical companies (or poppy plants grown for pharmaceutical use) and food manufacturers. Do brokers or other intermediary distributors request poppy seeds from specific cultivars of poppy plants? If so, what are these specific cultivars?

Question 8: Do brokers or other intermediary distributors typically sell poppy seeds direct to retailers or individual consumers? What additional precautions or steps are taken when selling directly to retailers or consumers?

C. Questions About Processing and Manufacturing From Poppy Plants to Poppy Seeds

We want additional information about other post-harvest practices conducted by manufacturers to control or reduce, or that may otherwise affect, poppy seed opiate alkaloid content, such as if opiate alkaloid testing (at any point) or poppy seed heat treatments are performed (Refs. 10–12). More information on the types of practices to reduce opiate alkaloids and frequency of the practices, as well as any evidence on their impact on the opiate alkaloid content of poppy seeds and the quality of the seeds, would be useful.

Question 9: What manufacturing processes are used to manufacture poppy seed food products and what processes are applied to reduce poppy seeds' opiate alkaloid content? Information about any processes, such as initial inspection, cleaning or separation of plant parts, mixing, crushing, blending, treatments such as heating or washing, drying, cleaning of equipment, cleaning frequency, packaging, testing, testing type, and transportation, used to process poppy seeds and manufacture poppy seed products would be useful.

Question 10: When using contract growers or otherwise procuring seeds, what specific varieties, cultivars, characteristics (*e.g.,* color, aroma, opiate alkaloid levels), or other specifications are typically required for food use?

Question 11: If you are a manufacturer of poppy seeds or poppy seed products, what types of customers (*e.g.,* manufacturers of other products, retailers, individual customers) do you sell to? What additional precautions or steps, if any, are taken when selling to various customers?

Question 12: If you are a manufacturer of poppy seeds or poppy seed products, what types of sellers (*e.g.,* manufacturers of other products, growers, other sources) do you buy poppy seeds from? What additional precautions or steps, if any, are taken when buying from various sellers?

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. Center for Science in the Public Interest Citizen Petition, February 5, 2021, Docket No. FDA–2021–P–0168).

*2. BfR (Bundesinstitut für Risikobewertung—Federal Institute for Risk Assessment), 2005. ''BfR Recommends Provisional Daily Upper Intake Level and a Guidance Value for Morphine in Poppy Seeds.'' BfR Health Assessment No. 012/2006, 27 December 2005. Available at *http://www.bfr.bund.de/cm/245/bfr_recommends_provisional_daily_upper_intake_level_and_a_guidance_value_for_morphine_in_poppy_seeds.pdf* (accessed September 13, 2024).

*3. European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM). ''Scientific Opinion on the Risks for Public Health Related to the Presence of Opium Alkaloids in Poppy Seeds.'' *EFSA Journal,* 9(11):2405, 2011. Available at *https://doi.org/10.2903/j.efsa.2011.2405* (accessed September 13, 2024).

*4. EFSA Panel on Contaminants in the Food Chain (CONTAM), et al. ''Update of the Scientific Opinion on Opium Alkaloids in Poppy Seeds.'' *EFSA Journal,* 16(5):e05243, 2018. Available at *https://doi.org/10.2903/j.efsa.2018.5243* (accessed September 13, 2024).

*5. European Union ''Commission Recommendation of 10 September 2014 on Good Practices to Prevent and to Reduce the Presence of Opium Alkaloids in Poppy Seeds and Poppy Seed Products.'' 2014/662/EU. Official Journal of the European Union, L271/96. Available at *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2014.271.01.0096.01.ENG&toc=OJ%3AL%3A2014%3A271%3ATOC* (accessed September 13, 2024).

*6. Fist, A.J. ''The Tasmanian Poppy Industry: A Case Study of the Application of Science and Technology.'' *Proceedings of the Australian Agronomy Conference.* 2001. Available at *https://nla.gov.au/nla.obj-1382338968/view* (accessed September 13, 2024).

7. Martinov, M. and M. Konstantinovic. ''Chapter 2: Harvesting,'' in *Medicinal and Aromatic Crops: Harvesting, Drying, and Processing.* Oztekin, S., Martino, M., The Hawthorn Press, Inc. 2007.

8. Fejér, J. and I. Salamon. ''Agro-Technology of the Poppy: Large-Scale Cultivation in Slovakia.'' *International Symposium on*

Papaver 1036. 2014.
9. Montgomery, M.T., X.A. Conlan, A.G. Theakstone, et al. ''Extraction and Determination of Morphine Present on the Surface of Australian Food Grade Poppy Seeds Using Acidic Potassium Permanganate Chemiluminescence Detection.'' *Food Analytical Methods,* 13(5):1159–1165, 2020. Available at *https://doi.org/10.1007/s12161-020-01729-z* (accessed December 8, 2024).
10. Lo, D. and T. Chua. ''Poppy Seeds: Implications of Consumption.'' *Medicine, Science and the Law,* 32(4):296–302, 1992. Available at *https://doi.org/10.1177/002580249203200403* (accessed December 8, 2024).
11. Sproll, C., R.C. Perz, R. Buschmann, et al. ''Guidelines for Reduction of Morphine in Poppy Seed Intended for Food Purposes.'' *European Food Research and Technology,* 226(1):307–310, 2007. Available at *https://doi.org/10.1007/s00217-006-0522-7* (accessed December. 8, 2024).
12. Shetge, S.A., M.P. Dzakovich, J.L. Cooperstone, et al. ''Concentrations of the Opium Alkaloids Morphine, Codeine, and Thebaine in Poppy Seeds are Reduced After Thermal and Washing Treatments But Are Not Affected When Incorporated in a Model Baked Product.'' *Journal of Agricultural and Food Chemistry,* 68(18):5241–5248, 2020. Available at *https://doi.org/10.1021/acs.jafc.0c01681* (accessed December 8, 2024).

Dated: January 8, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00757 Filed 1–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5964]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 23 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 23 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 February 14, 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.*

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 040454	Promethazine Hydrochloride (HCl) injectable, 25 milligrams (mg)/milliliters (mL) and 50 mg/mL.	Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Bldg. A, Parsippany, NJ 07054.
ANDA 040593	Promethazine HCl injectable, 25 mg/mL and 50 mg/mL	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 064042	Nystatin suspension, 100,000 units/mL	PAI Holdings, LLC, dba Pharmaceutical Associates, Inc., and dba PAI Pharma, 1700 Perimeter Rd., Greenville, SC 29605.
ANDA 074811	Haloperidol Decanoate injectable, Equivalent to (EQ) 50 mg base/mL.	Hikma Pharmaceuticals USA Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08003.
ANDA 076061	Pergolide Mesylate tablet, EQ 0.05 mg base, EQ 0.25 mg base, and EQ 1 mg base.	Strides Pharma Inc., U.S. Agent for Strides Pharma Global Pte Ltd., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.
ANDA 079075	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Bldg. A, Parsippany, NJ 07054.
ANDA 079240	Sumatriptan Succinate injectable, EQ 6 mg base/0.5 mL (EQ 12 mg base/mL) and EQ 4 mg base/0.5 mL (EQ 8 mg base/mL).	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 084591	Promethazine HCl injectable, 25 mg/mL	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.).
ANDA 090016	Irinotecan HCl injectable, 40 mg/2mL (20 mg/mL) and 100 mg/5 mL (20 mg/mL).	Hisun Pharmaceuticals USA Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.
ANDA 200536	Ranitidine HCl tablet, EQ 150 mg base	Strides Pharma Inc., U.S. Agent for Strides Pharma Global Pte Ltd.
ANDA 201745	Ranitidine HCl tablet, EQ 75 mg base	Do.
ANDA 204991	Atorvastatin Calcium tablet, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base, and EQ 80 mg base.	Lupin Pharmaceuticals, Inc., U.S. Agent for Lupin Ltd., Harborplace Tower, 111 South Calvert St., 21st Floor, Baltimore, MD 21202.
ANDA 205512	Ranitidine HCl tablet, EQ 150 mg base and EQ 300 mg base	Strides Pharma Inc., U.S. Agent for Strides Pharma Global Pte Ltd.
ANDA 206155	Olanzapine tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.	RegCon Solutions, LLC, U.S. Agent for Indoco Remedies Ltd., 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121.
ANDA 206204	Piperacillin and Tazobactam injectable, EQ 12 grams (g) base/vial; EQ 1.5 g base/vial.	Fresenius Kabi USA, LLC.
ANDA 207338	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Actavis Laboratories FL, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA Inc.), 400 Interpace Parkway, Bldg. A, Parsippany, NJ 07054.