The FD&C Act itself provides for misdemeanor liability under section 303(a)(1). Taken together, section 306(b)(2)(B)(i)(I) and (c)(3) prescribes the circumstances under which the Agency will exercise its discretion to debar individuals convicted of misdemeanors under the FD&C Act. Furthermore, in this case, the Agency has made the appropriate findings and considered the proper statutory criteria in evaluating the appropriateness and period of Thaxter's debarment. Accordingly, the Chief Scientist does not agree that Thaxter's debarment for 5 years violates his right to due process.

Thaxter next argues that debarring him for 5 years would be ''unreasonable and would not comport with the basic requirements of reasoned decision-making'' unless FDA were to justify ''the radical departure from precedent that debarring [him] would represent.'' He argues further that ''it would be arbitrary, capricious, and contrary to law for FDA to [debar] a party that has not taken action that poses a significant threat to the integrity of the regulatory system'' or ''not to hold a hearing to support its position.''

Based on Thaxter's arguments and the case law he cites, he appears to be relying on the judicial standard for review of Agency decision-making in the APA at 5 U.S.C. 706(2), which directs courts to ''hold unlawful and set aside agency action[s]'' that are ''arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'' As the Supreme Court has held, the question under that standard is whether the Agency has provided a reasonable explanation for the substance its decision:

> The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. Judicial review under that standard is deferential, and a court may not substitute its own policy judgment for that of the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision (*FCC* v. *Prometheus Radio Project,* 141 S. Ct. 1150, 1158, 209 L. Ed. 2d 287 (2021)).

In this matter, as reflected in the lengthy discussion above, the Agency has reasonably considered the relevant issues and fully explained its decision to debar Thaxter. Although Thaxter points to other individuals who pled guilty to misdemeanors based on liability as RCOs and who have not been debarred, he provides no details with respect to those individuals' convictions. Even assuming, however, that those individuals were similarly situated to him, his bare assertion that an Agency cannot choose to begin pursuing debarment of individuals for certain discrete categories of Federal misdemeanor convictions because it has not done so in the past is unfounded. As discussed, the terms of section 306(b)(2)(B)(i)(I) and (c)(3) of the FD&C Act are clear, and the Agency has exercised its discretion here in a manner consistent with the permissive debarment of many other individuals convicted of Federal misdemeanors. Accordingly, Thaxter's argument that debarring him is arbitrary, capricious, and contrary to law lacks merit.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to her by the Commissioner of Food and Drugs, finds that (1) Thaxter has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Thaxter is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Thaxter, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Thaxter, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Thaxter during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 21, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023–03941 Filed 2–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1046]

Wojciech Lesniak: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Wojciech Lesniak for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lesniak engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Mr. Lesniak was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of November 21, 2022 (30 days after receipt of the notice), Mr. Lesniak had not responded. Mr. Lesniak's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable February 27, 2023.

ADDRESSES: Any application by Mr. Lesniak for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*

▪ If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

▪ *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2022–N–1046. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4144), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer), that are not designated in an entry in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Lesniak has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at either the Miami or the Newark International Mail Facilities (IMF) and were addressed to Mr. Lesniak at an address connected to him.

On or about June 28, 2019, Mr. Lesniak offered for import a parcel intercepted and processed by FDA at the Newark IMF and which was addressed to him. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 280 tablets of BAYER ASPIRIN C (Acidum acetylsalicylicum 400 milligram (mg) + Acidum Ascorbicum 240 mg) and was refused entry on August 15, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR. 201.15(c)(1). FDA also determined that another product contained in this parcel was 360 tablets of APAP (paracetamolum 500 mg) tabletki powlekane. The product was refused entry on August 15, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR. 201.15(c)(1). FDA also determined that another product contained in this parcel was 300 tablets of APAP EXTRA (Paracetamolum 500 mg + Caffeinum 65 mg). The product was refused entry on August 15, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). The product was a misbranded drug pursuant to section 502(c) of the FD&C Act. FDA also determined that another product contained in this parcel was 156 tablets of ALTACET TABLETKI (Aluminii Acetas Tartas 1 gram (g)). The product was refused entry on August 15, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). All the products in this parcel were misbranded drugs pursuant to section 502(c) of the FD&C Act.

On or about July 02, 2019, Mr. Lesniak offered for import a parcel intercepted and processed by FDA at the Newark IMF and which was addressed to him. This parcel contained multiple products. The FDA determined that one of the products contained in this parcel was 600 g of MASC CYNKOWA (Zinc Oxidi urguentum) 10%. The product was refused entry on August 22, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1), and because the product appeared to be an over-the-counter drug without required labeling. FDA determined that one of the products contained in this parcel was 960 tablets of NO–SPA (Drotaverini hydrochloridum 40 mg). The product was refused entry on August 22, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1), and because the product appeared to be an over-the-counter drug without required labeling. FDA determined that one of the products contained in this parcel was 80 tablets of RANIGAST MAX (Ranitidinum 150 mg). The product was refused entry on August 22, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1), and because the product appeared to be an over-the-counter drug without required labeling. FDA determined that one of the products contained in this parcel was 3 packages of OROFAR TOTAL

ACTION (Benzoxonii chloridum + Lidocaini Hydrochloridum (2.5 mg + 1,5 mg/milliliters (ml))). The product was refused entry on August 22, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1), and because the product appeared to be an over-the-counter drug without required labeling. FDA determined that one of the products contained in this parcel was 10 packages of MASC ICHTIOLOWA (Ammonii Bituminosulfonatis Unguentum FP 10%). The product was refused entry on August 22, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1), and because the product appeared to be an over-the-counter drug without required labeling. All of the products in this parcel were misbranded drugs pursuant to section 502(c) of the FD&C Act.

On or about July 02, 2019, Mr. Lesniak offered for import another parcel intercepted and processed by the FDA at the Newark IMF and which was addressed to him. FDA determined that one of the products contained in this parcel was 530 tablets of RANIGAST MAX (Ranitidinum 150mg). The product was refused entry on August 23, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). FDA determined that one of the products contained in this parcel was 25 packages of LIOTON 1000 ZEL (Heparinum Natricum). The product was refused entry on August 23, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). FDA determined that one of the products contained in this parcel was 10 packages of MASC ICHTIOLOWA (Ammonii bituminosulfonatis unguentum FP). The product was refused entry on August 23, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). FDA determined that one of the products contained in this parcel was 20 packages of OPOKAN ACTIGEL (100mg/ml, zel Naproxenum). The product was refused entry on August 23, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). FDA determined that one of the products contained in this parcel was 3 packages of ALTACEL ZEL (Aluminii Acetotartras 10mg/g). The product was refused entry on August 23, 2019, because the product's required label or labeling appeared to not be in English, in violation of 21 CFR 201.15(c)(1). All the products in this parcel were misbranded drugs pursuant to section 502(c) of the FD&C Act.

On or about January 4, 2022, Mr. Lesniak offered for import another parcel intercepted and processed by FDA at the Miami IMF and which was addressed to him. FDA determined that one of the products contained in this parcel was 4 boxes of DIOHESPAN MAX and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English in violation of 21 CFR 201.15(c)(1) and the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 4 boxes of NEO–ANGIN and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 10 boxes of FURAGINUM and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 10 boxes of ALTACET and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 17 boxes of RUTINOSCORBIN and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and it was determined the drug is not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 10 boxes of ESPUMISAN MAX and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and it was determined the drug is not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 18 boxes of RAPHACHOLIN FORTE and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and it was determined the drug is not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 20 boxes of WEGIEL LECZNICZY and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and it was determined the drug is not included in a list required by section 510(j) of the FD&C Act. FDA determined that another one of the products contained in this parcel was 41 boxes of GRIPEX MAX and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and it was determined the drug was not included in a list required by section 510(j) of the FD&C Act. All the products in this parcel were destroyed on March 11, 2022.

On or about February 16, 2022, Mr. Lesniak offered for import a parcel intercepted and processed by the FDA at the Miami IMF and which was addressed to him. FDA determined that the product contained in this parcel was 42 boxes of FLEGAMINA CLASSIC and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1). The product was destroyed on March 11, 2022.

On or about February 16, 2022, Mr. Lesniak offered for import another parcel intercepted and processed by the FDA at the Miami IMF and which was addressed to him. FDA determined that the product contained in this parcel was 42 boxes of FLEGAMINA CLASSIC and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1). The product was destroyed on March 11, 2022.

On or about February 18, 2022, Mr. Lesniak offered for import a parcel intercepted and processed by the FDA at the Miami IMF and which was addressed to him. FDA determined that the product contained in this parcel was 42 boxes of FLEGAMINA CLASSIC and was a misbranded drug pursuant to section 502(c) of the FD&C Act because the product's required label or labeling was not in English, in violation of 21 CFR 201.15(c)(1), and it was determined

the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on March 22, 2022.

As a result of this pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act (21 U.S.C. 335a(b)(3)(D)), FDA sent Mr. Lesniak, by certified mail on October 17, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Lesniak's pattern of conduct and concluded that his conduct warranted the imposition of a five-year period of debarment. The proposal informed Mr. Lesniak of the proposed debarment and offered him an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Lesniak received the proposal and notice of opportunity for a hearing on October 22, 2022. Mr. Lesniak failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment. (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Wojciech Lesniak has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Lesniak is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Lesniak is a prohibited act.

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03958 Filed 2–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–1013]

Determination That CHANTIX (Varenicline Tartrate) Tablets, 0.5 Milligram and 1 Milligram, Has Not Been 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 CHANTIX (varenicline tartrate) tablets, 0.5 milligram (mg) and 1 mg, has not been withdrawn from sale for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6258, Silver Spring, MD 20993–0002, 301–796–8767, *David.Faranda@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 has been 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 approval of 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.

CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, is the subject of NDA 021928, held by PF Prism CV (c/o Pfizer Inc.), and initially approved on May 10, 2006. CHANTIX is indicated for use as an aid to smoking cessation treatment.

PF Prism CV has voluntarily discontinued marketing of CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg. The levels of the N-nitroso-varenicline (NNV) impurity in Chantix exceeded FDA's acceptable intake limit.[1] FDA's current understanding is

[1] Nitrosamine impurities in the drug supply are an important public health concern to which the Agency is dedicating significant resources. As explained in FDA's Guidance for Industry, *Control of Nitrosamine Impurities in Human Drugs,* ''Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer (IARC). They are referred to as ''cohort of concern'' compounds in the ICH guidance for industry *M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk* (March 2018).'' Many drug products have been found to contain levels of nitrosamines that are unacceptable or require further evaluation. FDA's current understanding is that nitrosamine levels in affected drug products have different causes and may be controlled using different strategies, including formulation design (*i.e.,* adding antioxidants or adding pH adjusters that modify the microenvironment to base or neutral pH) and supplier qualification programs.