I. Background

On December 17, 2014, FDA published a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data Guidance), posted on FDA's Study Data Standards Resources Web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The eStudy Data Guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act for study data contained in NDAs, ANDAs, BLAs, and certain INDs to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

FDA currently supports the use of WHODG for the coding of concomitant medications in studies submitted to CBER or CDER in NDAs, ANDAs, BLAs, and certain INDs in the electronic common technical document format. Generally, the studies included in a submission are conducted over many years and may have used different WHODG versions to code concomitant medications. The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support of the most current B3-format annual version of WHODG is March 15, 2018. Although the use of the current B3-format annual version of WHODG is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the ''date requirement begins.'' The Study Data Technical Conformance Guide provides addition information and recommendations on the coding of concomitant medications (*https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm384744.pdf*).

FDA support for earlier versions of WHODG will end for studies that start after March 15, 2019. The Catalog will be updated to list March 15, 2019, as the ''date support ends.'' Studies that start after March 15, 2019, will be required to use the most current B3-format annual version of WHODG.

Dated: October 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23029 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0278]

Trand Doan Nguyen; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Trang Doan Nguyen's (Nguyen's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Nguyen for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Nguyen was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Nguyen's debarment, FDA has considered the relevant factors listed in the FD&C Act. Nguyen has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective October 24, 2017.

ADDRESSES: Any application by Nguyen for special termination of debarment under section 306(d) of the FD&C Act (application) 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

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 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: Your application must include the Docket No. FDA–2011–N–0278. An application will be placed in the docket and, unless 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Nathan R. Sabel, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993, 301–796–8588.

SUPPLEMENTARY INFORMATION:

I. Background

On December 12, 2008, in the U.S. District Court for the District of Missouri, Nguyen pled guilty to a misdemeanor for introducing a misbranded drug into interstate commerce in violation of sections 301(a) and 303(a)(1) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(1)). The basis for Nguyen's guilty plea was her admission that she repackaged unapproved versions of the drugs LIPITOR and CELEBREX, some of which were counterfeit, and relabeled them in a manner that did not disclose that they were unapproved or that they were counterfeit and then shipped them to other States. The drugs were misbranded under section 502(a) of the FD&C Act (21 U.S.C. 352(a)) in that their labeling was false and misleading.

Nguyen is subject to debarment based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)): (1) That she was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs. By letter dated July 6, 2011, FDA served Nguyen a notice proposing to debar her for 5 years from providing services in any capacity to a person having an approved or pending drug product application and providing an opportunity for Nguyen to request a hearing. In a letter dated July 29, 2011, Nguyen requested a hearing on the proposal. In her request for a hearing, Nguyen acknowledges her conviction under Federal law, as stated by FDA in the proposal to debar. However, she argues that the proposal to debar her contains material inaccuracies with respect to certain facts related to her misdemeanor conviction.

The Directors of the Office of Scientific Integrity (OSI) reviewed Nguyen's request for a hearing, as well as the materials offered in support, and find that Nguyen has not created a basis for a hearing because hearings will be granted only if there is a genuine and substantial issue of fact for resolution at a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

The Director of OSI has considered Nguyen's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

Nguyen raises a number of arguments in support of her hearing request. She does not appear, however, to dispute that she is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act. As noted above, to debar Nguyen under section 306(b)(2)(B)(i)(I), FDA must find both: (1) That Nguyen was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs. As set forth in the proposal to debar Nguyen, her Federal misdemeanor conviction involved a violation of the FD&C Act's requirements for drugs. As a result, the conduct underlying her conviction both related to the regulation of drug products under the FD&C Act and undermined the process for the regulation of drugs. Nguyen does not contradict the findings to that effect in the proposal to debar and has thus failed to create a material factual dispute with respect to whether she is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

In her request for a hearing, Nguyen argues nonetheless that she is entitled to a hearing because, in the proposal to debar, FDA relied on findings that are not supported by the record in determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act. Under section 306(i) of the FD&C Act, FDA may not take any action under sections 306(b) or section 306(c) with respect to any person ''unless [FDA] has issued an order for such action made on the record after opportunity for agency hearing on disputed issues of material fact.'' Section 306(c)(3) explicitly requires FDA to consider, ''where applicable,'' certain factors ''[i]n determining the appropriateness and the period of debarment'' for any permissive debarment. The proposal to debar Nguyen set forth four applicable considerations under section 306(c)(3): (1) The nature and seriousness of her offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps taken to mitigate the impact on the public under section 306(c)(3)(C); and (4) prior convictions involving matters within the jurisdiction of FDA under section 306(c)(3)(F) of the FD&C Act. In the proposal, FDA found that the first three considerations weigh in favor of debarring Nguyen and noted that the fourth consideration would be treated as a favorable factor for her because the Agency was unaware of any prior convictions involving matters within the jurisdiction of FDA.

Nguyen's challenge to specific findings in the proposal to debar fails to create a genuine and substantial dispute of fact for resolution at a hearing with respect to any of the applicable considerations under section 306(c)(3) of the FD&C Act. In her request for a hearing, Nguyen argues that the records of her criminal proceedings do not support certain findings in the proposal to debar. Specifically, she contends that neither the plea agreement nor the criminal information to which she pled guilty support the following findings: (1) That she was ''aware that the drugs [in question] needed to be relabeled for sale in the United States,'' (2) that some of the drugs bore labeling in Portuguese before they were relabeled, or (3) that the conduct underlying her conviction continued for 13 months. Even after disregarding the findings in the proposal to debar to which Nguyen objects, we find that she should be debarred for the maximum period of 5 years.

Nguyen's factual objections relate primarily to the consideration of the nature and seriousness of her offense under section 306(c)(3)(A) of the FD&C

Act. As noted previously, Nguyen pled guilty to a misdemeanor under the FD&C Act by admitting that she acquired, repackaged, relabeled, and distributed unapproved prescription drugs in interstate commerce. In her criminal proceedings, Nguyen also admitted that some of these unapproved prescription drugs were counterfeit drugs. By definition, a counterfeit drug is a drug whose container or labeling falsely describes the manufacturer, processer, packer, or distributer of that drug (*see* 21 U.S.C. 331(g)(2)) and thereby can effectively conceal the actual manufacturer, processer, packer, or distributer from consumers and government regulators. An unapproved drug in this context is a drug requiring but lacking FDA approval that is not generally recognized as safe and effective for its intended use (*see* 21 U.S.C. 331(g)(1)). As such, the products that Nguyen admitted to acquiring, repackaging, relabeling, and further distributing were not simply misbranded in some technical sense.

With respect to Nguyen's assertion that her offense was committed without knowledge, section 306(b)(2)(B)(i) of the FD&C Act specifically provides for the debarment of individuals convicted of Federal misdemeanors related to the regulation of drug products under the FD&C Act. Given that a misdemeanor violation of the FD&C Act itself is a strict liability offense, meaning an offense that does not require proof of knowledge as an element of the crime, it stands to reason that criminal intent is not required to subject an individual to debarment under section 306(b)(2)(B)(i). As recognized by the U.S. Supreme Court, an individual who is responsible for the operation of an FDA-regulated business is also responsible for any violations of the FD&C Act that arise out of the conduct of the business, whether or not he or she intends to commit the violations or even knows that the violations have been committed. (*United States* v. *Park,* 421 U.S. 658 (1975); *United States* v. *Dotterweich,* 320 U.S. 277 (1943)). In keeping with the FD&C Act's purpose of protecting the public from adulterated and misbranded products, Congress chose to place the burden of protecting the public on those who manufacture and distribute those products rather than on consumers, who cannot protect themselves. (*Dotterweich,* 320 U.S. at 280–81.) Nguyen herself chose to run a business that acquired, repackaged, relabeled, and further distributed prescription drugs to consumers who were unable to protect themselves from the unapproved and counterfeit products that Nguyen admitted to providing them.

Even though the law subjects Nguyen to permissive debarment as a responsible corporate officer regardless of her knowledge or intent to commit the violation, Nguyen has admitted that she personally engaged in the conduct underlying the violation as a hands-on participant. Nguyen admitted in her plea that she repackaged the drugs and affixed labeling to these prescription drugs that did not disclose that the drugs were counterfeit and not approved by FDA. Nguyen admitted that she repackaged and affixed this false and misleading labeling to these prescription drugs and then shipped these drugs in interstate commerce for eventual use by the unknowing public. In light of these undisputed and admitted facts, even crediting Nguyen's objections related to her level of knowledge, the precise language of the product labeling on some of the drugs she received, and the precise length of time she committed this offense, these objections do not minimize the nature and seriousness the conduct Nguyen both committed and admitted. The proposal to debar alleges that Nguyen's conduct ''created a significant risk of injury to consumers who were exposed to misbranded drugs and seriously undermined the integrity of the Agency's regulation of drug products.'' Because of the uncontested and admitted facts already discussed, Nguyen's objections, even if taken as true, would not undermine this conclusion. Therefore, we conclude that the nature and seriousness of her conduct weighs in favor of debarring Nguyen.

Having found that the consideration in section 306(c)(3)(A) of the FD&C Act weighs in favor of debarring Nguyen, we turn to the remaining three applicable considerations. Nguyen does not dispute the unfavorable facts in the FDA proposal to debar that relate to the considerations in sections 306(c)(3)(B) and (C) of the FD&C Act. Specifically, Nguyen does not dispute the findings in the proposal that she used a company of which she was the owner and operator, AQ Pharmaceuticals, Inc., to distribute the unapproved and counterfeit drugs and that she served in a managerial role in this offense. Nor does Nguyen contradict the findings in the proposal to debar that she and her company did not discontinue their illegal conduct until it was discovered by authorities. In her hearing request, Nguyen does not point to any voluntary steps taken to mitigate the effect of her offenses on the public. Thus, the considerations in sections 306(c)(3)(B) and (C) of the FD&C Act regarding Nguyen's management role and the voluntary steps taken by Nguyen to mitigate the impact of her offense on the public both weigh in favor of her debarment. Although Nguyen appears to have no previous criminal convictions related to matters within the jurisdiction of FDA (*see* section 306(c)(3)(F) of the FD&C Act), this consideration alone does not counter to a sufficient degree the nature and seriousness of the conduct underlying her misdemeanor conviction, her managerial role in the offense, and the lack of any voluntary steps taken to mitigate the impact of that offense of the public, to warrant decreasing the period of debarment from 5 years.

III. Findings and Order

Therefore, the Director of OSI, under section 306(b)(1)(B)(i)(I) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds that Nguyen has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the regulation of drugs. FDA has considered the relevant 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, Nguyen is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 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**) (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 Nguyen, in any capacity during her period of debarment, will be subject to civil money penalties. If Nguyen, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Nguyen during her period of debarment.

Dated: October 19, 2017.

G. Matthew Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2017–23019 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5715]

Watson Laboratories, Inc., and Barr Laboratories, Inc., Subsidiaries of Teva Pharmaceuticals USA, Inc.; Withdrawal of Approval of 54 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 54 abbreviated new drug applications (ANDAs) from two applicants. The holders of the applications 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 November 24, 2017.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION: The holders of the applications 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 abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
ANDA 061717	Doxycycline Hyclate Capsules USP, Equivalent to (EQ) 50 milligrams (mg) base and EQ 100 mg base.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 062087	Erythromycin Estolate Capsules USP, EQ 250 mg base	Do.
ANDA 062318	Gentamicin Injection USP, EQ 10 mg base/milliliter (mL) and EQ 40 mg base/mL.	Do.
ANDA 062816	Ampicillin for Injection USP, EQ 125 mg base/vial, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial.	Do.
ANDA 062994	Ampicillin for Injection USP, EQ 10 g base/vial	Do.
ANDA 062999	Erythromycin Delayed-Release Tablets USP, 500 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 064036	Cefuroxime for Injection USP, EQ 7.5 g base/vial	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070296	Diazepam Injection USP, 5 mg/mL	Do.
ANDA 070412	Furosemide Tablets USP, 20 mg	Do.
ANDA 070435	Ibuprofen Tablets USP, 200 mg	Do.
ANDA 070436	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 070437	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 070449	Furosemide Tablets USP, 20 mg	Do.
ANDA 070450	Furosemide Tablets USP, 40 mg	Do.
ANDA 070515	Tolazamide Tablets USP, 500 mg	Do.
ANDA 070528	Furosemide Tablets USP, 80 mg	Do.
ANDA 071238	Doxepin Hydrochloride (HCl) Capsules USP, EQ 50 mg base	Do.
ANDA 071547	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 072397	Diazepam Injection USP, 5 mg/mL	Do.
ANDA 072407	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072602	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072630	Albuterol Tablets USP, EQ 4 mg base	Do.
ANDA 072825	Baclofen Tablets USP, 20 mg	Do.
ANDA 073013	Metaproterenol Sulfate Tablets USP, 10 mg	Do.
ANDA 073445	Meperidine HCl Injection USP, 100 mg/mL	Do.
ANDA 074025	Guanabenz Acetate Tablets USP, EQ 4 mg base and EQ 8 mg base	Do.
ANDA 074114	Dobutamine Injection USP, EQ 12.5 mg base/mL	Do.
ANDA 074163	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074287	Piroxicam Capsules USP, 10 mg and 20 mg	Do.
ANDA 074303	Pentamidine Isethionate for Injection, 300 mg/vial	Do.
ANDA 074437	Pindolol Tablets USP, 5 mg and 10 mg	Do.
ANDA 074456	Alprazolam Tablets USP, 0.25 mg, 0.5 mg, and 1 mg	Do.
ANDA 077643	Topiramate Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg	Do.
ANDA 080728	Diphenhydramine HCl Capsules USP, 25 mg	Do.
ANDA 080968	Dexamethasone Tablets USP, 0.75 mg	Do.
ANDA 081040	Chlorzoxazone Tablets USP, 500 mg	Do.
ANDA 081149	Hydroxyzine HCl Tablets USP, 10 mg	Do.
ANDA 081189	Hydrochlorothiazide Tablets USP, 25 mg	Do.
ANDA 081216	Estropipate Tablets USP, 6 mg	Do.
ANDA 083232	Hydrochlorothiazide Tablets USP, 50 mg	Do.