

device, food additive, or color additive products regulated by the FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the

length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with "due diligence."

The statute defines due diligence as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." As provided in § 60.30(c), a due diligence petition "shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence." Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is

published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 15 requests for revision of the regulatory review period have been submitted under § 60.24(a). For 2010, 2011, and 2012, a total of three requests have been submitted under § 60.24(a). During that same time period, there have been no requests under §§ 60.30 and 60.40; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
60.24(a)	1	1	1	100	100
60.30	1	1	1	50	50
60.40	1	1	1	10	10
Total	160

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-27226 Filed 11-13-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-N-0110]

Bruce I. Diamond; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Dr. Bruce I. Diamond's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act

(the FD&C Act) debaring Dr. Diamond for 10 years from providing services in any capacity to a person who has an approved or pending drug product application. FDA bases this order on findings that Dr. Diamond was convicted of felonies under State 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, was convicted of felonies involving fraud, and was a material participant in acts forming the basis of a conviction that subjects another person to debarment. In determining the appropriateness and length of Dr. Diamond's debarment period, FDA has evaluated the relevant considerations listed in the FD&C Act. Dr. Diamond has failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective November 14, 2013.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4613.

SUPPLEMENTARY INFORMATION:

I. Background

On December 16, 1997, Dr. Diamond pled guilty to 53 State criminal offenses, including felonies, in the Superior Court for the County of Richmond, Georgia, and the court subsequently entered judgment against him. The offenses in the Official Code of Georgia to which

Dr. Diamond pled guilty included 16 counts of theft by taking (section 16–8–2), 10 counts of theft of services (section 16–8–5), 2 counts of written false statements (section 16–10–20), 8 counts of acquiring a controlled substance by misrepresentation (section 16–13–43), 8 counts of prescribing or ordering dangerous drugs (section 16–13–78.1), 7 counts of prescription of controlled substances (section 16–13–41(f)), 1 count of practicing medicine without a license (section 43–34–26), and 1 count of bribery (section 16–10–2). On February 10, 1999, in a separate proceeding, Dr. Diamond consented to disqualification from receiving investigational new drugs under § 312.70(b) (21 CFR 312.70(b)).

Dr. Diamond, who holds a doctorate in pharmacology but not a medical degree, was a professor on the faculty of the Medical College of Georgia (MCG), a unit of the Board of Regents of the University System of Georgia. Dr. Diamond collaborated with a colleague there, Richard Borison, M.D., Ph.D., to manage clinical trials for various drug companies. Without the knowledge or consent of MCG, Drs. Diamond and Borison used MCG and other government-owned facilities and State employees to conduct the clinical trials but diverted the funds paid by the study sponsors for their own gain, without compensating the university system. Although Dr. Diamond is not a physician, he managed medical aspects of the clinical trials. In that capacity, he signed Dr. Borison's name on prescriptions for controlled substances and other drugs the State defined as dangerous. During the course of one clinical trial, Drs. Borison and Diamond bribed an employee not to report to MCG an attempted suicide by one of the study subjects.

By notice dated November 26, 2002, FDA proposed to debar Dr. Diamond for 10 years from providing services in any capacity to a person having an approved or pending drug product application. The notice explained that the proposal was based on three separate grounds: (1) Dr. Diamond was convicted of felonies under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the FD&C Act, and the type of conduct serving as the basis of his convictions undermines the process for the regulation of drugs (section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I))); (2) Dr. Diamond was convicted of felonies involving bribery, fraud, and false statement, and, on the basis of the

convictions and other information, demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the FD&C Act relating to drug products (section 306(b)(2)(B)(ii)(I); and (3) Dr. Diamond materially participated in acts that were the basis of Dr. Borison's conviction of offenses subjecting Dr. Borison to debarment under section 306(b)(2)(B)(ii) and Dr. Diamond's participation, and other information, demonstrate a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the FD&C Act relating to drug products (section 306(b)(2)(B)(iii)). The notice to Dr. Diamond also outlined findings with respect to four factors that were considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of the offense, (2) the nature and extent of management participation in the offense, (3) the nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the FD&C Act or other acts involving matters within the jurisdiction of FDA.

By letter dated January 2, 2003, through counsel, Dr. Diamond requested a hearing on the proposal to debar. On February 17, 2004, after FDA granted him extensions, Dr. Diamond submitted a "final response" in support of his request for a hearing on the proposal to debar. In his response, Dr. Diamond argues: (1) That his consent agreement for disqualification under § 312.70(b) precludes his debarment, (2) that he is innocent of the charge of bribery, (3) that he is innocent of the charges involving drug prescribing, (4) that assertions that he used unqualified personnel to staff clinical trials are without justification or support, (5) that research subject safety was not compromised under his supervision, and (6) that he did not serve in a managerial role for the criminal conduct because Dr. Borison exercised control over him at all times.

Hearings are granted only if there is a genuine and substantial issue of fact. 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 or the action requested (see § 12.24(b) (21 CFR 12.24(b))).

The Chief Scientist has considered Dr. Diamond's arguments and concludes that they are unpersuasive and fail to

raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In support of his hearing request, Dr. Diamond presents six issues that we will presume are intended to call into question whether he is subject to debarment—and, if so, whether FDA should debar him—on the basis of any of the three grounds, section 306(b)(2)(B)(i)(I), (b)(2)(B)(ii)(I), and (b)(2)(B)(iii) of the FD&C Act, upon which FDA relied. We therefore address each of his arguments as a challenge to the grounds for debarment or to FDA's conclusions regarding the considerations in section 306(c)(3) of the FD&C Act, as appropriate.

A. Disqualification Consent Agreement

Dr. Diamond first argues that the consent agreement for his disqualification from receiving investigational drugs under § 312.70(b) precludes his debarment under section 306 of the FD&C Act. In support, he contends that the consent agreement "should have precluded any further administrative action against [him]."

The consent agreement states that the "agreement closes FDA's administrative proceedings *in the present matter*" (emphasis added). A debarment action under section 306 of the FD&C Act is an entirely separate matter from disqualification proceedings. FDA has the authority to disqualify a researcher from conducting clinical testing of new drugs when it determines that the researcher has repeatedly or deliberately not followed regulations intended to protect study subjects and ensure data integrity. (See § 312.70(a).) FDA also may debar from the drug industry individuals involved in certain conduct. Once an individual has been debarred, he may no longer provide services in any capacity for anyone with a drug product application that is approved or pending at FDA. (See section 306(a) and (b) of the FD&C Act.)

Furthermore, the consent agreement itself does not foreclose other types of administrative actions, such as debarment under section 306 of the FD&C Act. Finally, there is no statutory basis for concluding that the Agency's decision to disqualify Dr. Diamond from receiving investigational drugs under a separate process precludes his debarment. Accordingly, we conclude that there is no genuine and substantial issue of fact for resolution at a hearing and that the consent agreement regarding Dr. Diamond's disqualification does not prevent his debarment. (See § 12.24(b)(1).)

B. Debarment Under Section 306(b)(2)(B)(i)(I) or 306(b)(2)(B)(ii)(I) of the FD&C Act

Dr. Diamond's next two arguments focus on the conduct underlying his convictions for bribing an employee not to report an attempted suicide by a study subject and unlawfully acquiring and prescribing controlled substances and dangerous drugs. Dr. Diamond does not deny that he was convicted of those offenses, nor does he dispute that this type of conduct subjects him to permissive debarment under the FD&C Act. Rather, he argues that he is innocent of the charges and that "due to his need to reach a plea agreement with the State of Georgia to the charges that he misappropriated money from the State, he entered in to a complex and not wholly supported in fact plea agreement" and he "accepted perhaps too much when he pled guilty."

Section 306(b)(2)(B)(i)(I) of the FD&C Act provides FDA with authority to debar an individual who has been convicted of certain State felonies, if the Agency finds that the type of conduct serving as the basis for the conviction undermines the process for the regulation of drugs. The relevant factual issues are whether Dr. Diamond was, in fact, convicted of a felony under State law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of drug products under the FD&C Act and whether that type of conduct undermines the process for the regulation of drugs. Dr. Diamond does not dispute that he pled guilty to bribery and unlawful prescriptions for controlled substances and dangerous drugs or that this type of conduct undermines the process for the regulation of drugs. Dr. Diamond has therefore failed to show that a genuine and substantial factual dispute exists with respect to FDA's finding that he is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

In the alternative, section 306(b)(2)(B)(ii)(I) of the FD&C Act provides FDA with authority to debar an individual who has been convicted of a felony involving, among other things, bribery, false statements, or fraud, if the Agency finds that the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. The relevant factual issues are whether Dr. Diamond was convicted of a felony involving bribery, false statements, or fraud and whether he has demonstrated a pattern of conduct sufficient to find that there is reason to

believe he may violate requirements under the FD&C Act relating to drug products. Dr. Diamond does not dispute that he pled guilty to felonies involving bribery, false statement, and fraud, namely theft of over \$10 million from MCG by an 8-year pattern of deception, bribing an employee, making written false statements, acquiring controlled substances by misrepresentation, prescribing dangerous drugs and controlled substances while not being a registered practitioner, and practicing medicine without a license. FDA further determined that the type of conduct underlying Dr. Diamond's felony convictions, which were based on the 8-year conspiracy to defraud MCG through a scheme involving clinical studies, demonstrated "a pattern of conduct sufficient to find that there is reason to believe [Dr. Diamond] may violate requirements relating to drug products again." This determination was based on the nature of the conduct underlying the offenses to which Dr. Diamond pled guilty. Dr. Diamond has therefore failed to show that a genuine and substantial factual dispute exists with respect to FDA's finding that he is subject to debarment under section 306(b)(2)(B)(ii)(I) of the FD&C Act.

Section 306(I) of the FD&C Act includes in its definition of a conviction, a guilty plea. Accordingly, Dr. Diamond's arguments regarding the factual circumstances underlying his plea fail to raise a genuine and substantial issue of fact as to whether he was convicted of a felony under State 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 or whether he was convicted of a felony involving bribery, false statements, or fraud. Dr. Diamond contends that his plea agreement was "not wholly supported in fact." In his Written Plea of Guilty, however, Dr. Diamond states that "of my own free will I want to plead guilty today to the offenses [enumerated] . . . know and understand that I do not have to say, sign, or do anything that will show or tend to show that I am guilty unless I want to . . . My decision to plead guilty is freely and voluntarily made . . . I did in fact commit the offenses of which I am charged. I am in fact guilty as charged in the indictment and am in fact guilty of the charges I am pleading guilty to." He also stated that he was advised by competent counsel regarding his constitutional and due process rights. He was examined by the court during a lengthy plea colloquy. Under these circumstances, and in light of the

court's acceptance of his guilty plea, Dr. Diamond's allegations that he was actually innocent of the offenses and that he signed a plea agreement that was not wholly truthful are insufficient to create a genuine and substantial issue of fact for resolution at a hearing. (See § 12.24(b)(1) and (b)(2).) Therefore, Dr. Diamond is subject to debarment.

C. Debarment Under Section 306(b)(2)(B)(iii) of the FD&C Act

Finally, FDA found that Dr. Diamond is subject to debarment under section 306(b)(2)(B)(iii) of the FD&C Act for his material participation in the acts that resulted in another's conviction for an offense described in section 306(b)(2)(B)(i)(I) and that on that basis, Dr. Diamond had demonstrated a pattern of conduct sufficient to support a belief that he would violate requirements under the FD&C Act relating to drug products. On September 30, 2003, FDA debarred Dr. Diamond's co-conspirator, Dr. Borison, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, for his conviction of felonies under State law for racketeering, theft, and false statements and representations. (See *Richard L. Borison; Debarment Order*, 68 FR 56298 (September 30, 2003).) Dr. Diamond does not deny his material participation in the conduct that led to Dr. Borison's conviction. In particular, he does not deny participating with Dr. Borison in the theft of over \$10 million from MCG via an 8-year pattern of deception involving clinical trials. Furthermore, he does not dispute that his behavior demonstrates a pattern of conduct sufficient to support a finding that he would violate requirements under the FD&C Act relating to drug products. Dr. Diamond has therefore failed to show that a genuine and substantial factual dispute exists with respect to FDA's finding that he is subject to debarment under section 306(b)(2)(B)(iii) of the FD&C Act.

D. Debarment Considerations

Next, we construe Dr. Diamond's arguments regarding his innocence of the charges of bribery and unlawful prescriptions to be challenges to FDA's findings with respect to the debarment considerations of section 306(c)(3) of the FD&C Act. Dr. Diamond's arguments regarding the training and qualifications of the staff he oversaw as part of his criminal scheme and the safety of the subjects who participated in the clinical studies also seem to be directed at those findings. As noted previously, he also challenges FDA's finding that he participated as a manager in the offenses involved because, he claims, Dr. Borison

controlled him and masterminded the entire criminal operation.

Section 306(c)(3) of the FD&C Act requires that FDA consider, “where applicable,” certain factors “[i]n determining the appropriateness and the period of debarment” for any permissive debarment. The proposal to debar Dr. Diamond set forth four applicable considerations under section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of his 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).

In its proposal to debar, FDA presented factual findings relevant to each of the considerations. FDA determined, under section 306(c)(3)(A) of the FD&C Act, that the nature and seriousness of Dr. Diamond’s offenses weighed in favor of debarment because of the scope of his criminal conduct, his prescription of drugs without a practitioner’s license, and his direction of inadequately trained staff to perform medical procedures, creating a risk of injury. The Agency found, under section 306(c)(3)(B) of the FD&C Act, that Dr. Diamond’s management participation in the offenses weighed in favor of debarment. The Agency found that Dr. Diamond was a manager in that he “plann[ed] . . . , directed, and initiated the conduct underlying [his] conviction” and “directed other MCG employees to recruit subjects and participate in the conduct of the clinical studies.” Under section 306(c)(3)(C) of the FD&C Act, the Agency determined that, although Dr. Diamond cooperated with the authorities once they discovered his criminal scheme, he did not “promptly disclose to authorities all wrongdoing” and exhibited a wanton disregard for the public health by bribing an employee to remain silent about a suicide attempt. This factor also was found to weigh in favor of disbarment. Finally, relating to section 306(c)(3)(F) of the FD&C Act, FDA noted that the Agency is unaware of any prior convictions under the FD&C Act, a favorable factor.

Dr. Diamond first appears to challenge these findings by arguing that he is actually innocent of the bribery and unlawful prescriptions charges. As noted previously, however, his claims of actual innocence do not create a genuine and substantial issue of fact, as they must to justify a hearing under § 12.24(b). Dr. Diamond pled guilty to

those offenses in Federal Court, and he is bound by his guilty pleas, notwithstanding his current arguments that he pled guilty to those offenses only for strategic reasons.

Dr. Diamond also contests the Agency’s characterization of the conduct underlying his criminal convictions, as well as his material participation in the offenses committed by Dr. Borison. However, in pleading guilty to 52 criminal offenses, Dr. Diamond admitted to certain conduct. The conduct to which he admitted during the plea colloquy included overseeing a staff of nine employees to assist in running the clinical trials, bribing an employee not to report an adverse event, and prescribing controlled substances without a medical license. The offenses to which Dr. Diamond pled guilty stemmed from an 8-year scheme to deceive a medical college and his concurrent disregard for the protection of patients afforded by State laws.

By contending that the employees he oversaw did, in fact, have adequate training in drawing blood and that his conduct did not compromise the safety of any patients, Dr. Diamond is challenging FDA’s proposed findings regarding the nature and seriousness of any offenses involved under section 306(c)(3)(A) of the FD&C Act and the nature and extent of voluntary steps taken to mitigate the effect on the public under section 306(c)(3)(C). Even assuming, as Dr. Diamond now argues, that the nine employees he oversaw had received adequate training in drawing blood and that no patient was actually harmed by Dr. Diamond’s conduct, the 8-year scheme in which he participated still evinces both a clear disregard for the laws designed to protect patients and the public at large and a willingness to commit fraud in furtherance of his own financial gain. Dr. Diamond had 8 years to voluntarily mitigate the effects of his wrongdoing but failed even to modify his behavior to protect the public. Furthermore, Dr. Diamond’s arguments that he did not compromise the safety of his patients are belied by his convictions for violating numerous State criminal statutes clearly aimed at protecting patients, such as practicing medicine without a license and unlawfully acquiring and prescribing controlled or dangerous drugs. In short, given the scope of Dr. Diamond’s conduct, his current claims regarding the training of his employees and the safety of his patients are inadequate to create a genuine and substantial issue of fact with respect to the considerations in sections 306(c)(3)(A) and (c)(3)(C) or,

more generally, the appropriateness or period of his proposed debarment.

Finally, Dr. Diamond challenges the Agency’s findings under section 306(c)(3)(B) of the FD&C Act that he participated as a manager in his offenses by arguing that Dr. Borison exercised control over him and masterminded the criminal scheme. As noted previously and as outlined in the indictment to which he pled guilty, however, Dr. Diamond served a managerial role in the offenses. Even assuming, as Dr. Diamond now alleges, that he was at all times second in command to Dr. Borison, Dr. Diamond admitted during his criminal proceedings that he oversaw a staff of a least nine employees in implementing the criminal scheme of which he was convicted. Furthermore, he does not dispute the findings in the proposal to debar that he, along with Dr. Borison, was involved in planning and initiating the criminal scheme. Dr. Diamond’s claim that he was “at all times subservient to Dr. Borison” fails to present a genuine and substantial issue of fact with respect to the consideration in section 306(c)(3)(B) of the FD&C Act or, more generally, the appropriateness or period of his proposed debarment.

Consistent with the findings in the proposal to debar, the Chief Scientist finds, based on the undisputed record before the Agency, that debarment of Dr. Diamond for two consecutive terms of 5 years is appropriate. The considerations in section 306(c)(3)(A), (c)(3)(B), and (c)(3)(C) of the FD&C Act weigh in favor of debarring Dr. Diamond for at least 10 years. Although Dr. Diamond 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), that consideration does not counter to a sufficient degree the remaining considerations to warrant decreasing the periods of debarment. Of particular note are the nature and seriousness of Dr. Diamond’s offenses. As detailed previously, Dr. Diamond pled guilty to an 8-year criminal scheme reflecting not only, as found in the proposal to debar, “a wanton disregard for the public health,” but also a willingness to defraud a government body over a sustained period of time. Reducing the period of debarment from 10 years to some lesser amount of time based on Dr. Diamond’s lack of prior criminal convictions would be inconsistent with protecting the public health and thus the remedial purpose of the Agency’s debarment authority under section 306 of the FD&C Act.

II. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C

Act, or in the alternative section 306(b)(2)(B)(ii)(I) and (b)(2)(B)(iii) and under authority delegated to him, finds that Dr. Diamond is subject to debarment. The Chief Scientist has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that debarment for 10 years is appropriate.

As a result of the foregoing findings, Dr. Diamond is debarred for 10 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 Dr. Diamond, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. Diamond, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Diamond during his period of debarment.

Any application by Dr. Diamond for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2000-N-0110 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov/>.

Dated: November 4, 2013.

Jesse L. Goodman,
Chief Scientist.

[FR Doc. 2013-27186 Filed 11-13-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1279]

Medical Device Development Tools; Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Device Development Tools.” This document provides guidance to FDA staff, industry, healthcare providers, researchers, and patient and consumer groups on a new voluntary process within the Center for Devices and Radiological Health (CDRH) for qualification of medical device development tools (MDDT) for use in device development and evaluation programs. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 12, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Medical Device Development Tools” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Kathryn O’Callaghan, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3614, Silver Spring, MD 20993-0002, 301-796-6349.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance describes the framework and process for the voluntary CDRH qualification of MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, the threshold for qualification, and the contents of a qualification submission. The intent of this voluntary qualification policy is to: (1) Enable faster, more efficient development of important life-saving and health-promoting medical devices; (2) promote the development of tools to facilitate more timely device evaluation; (3) provide a mechanism to better leverage advances in regulatory science; and (4) more quickly and more clearly communicate with CDRH stakeholders about important advances in regulatory science that may be leveraged to speed device development and regulatory evaluation. CDRH expects the qualification process to expedite development of publicly available tools which could potentially be used widely in multiple device development programs. Once an MDDT is qualified for a specific context of use, it can be used by any medical device developer for that context of use.

At some point in the future, FDA may initiate a pilot program for MDDT qualification submissions, which would help inform final guidance on this topic. FDA would publicly announce such a program prior to initiation.

This guidance does not discuss the review of MDDTs submitted as part of a specific medical device regulatory submission, nor does it address the specific evidentiary standards or performance requirements needed for purposes of qualification of a specific MDDT.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the qualification of MDDTs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all