Date: March 31, 2015.
Time: 8:00 a.m. to 9:00 p.m.
Agenda: To review and evaluate cooperative agreement applications.
Place: Residence Inn Washington DC, 1199 Vermont Avenue NW., Washington, DC 20005.
Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–0229, *kenneth.ryan@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pregnancy/Neonatology Research.
Date: March 31, 2015.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *gary.hunnicutt@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Innovative Molecular Analysis Technology.
Date: March 31, 2015.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594–2414, *huzhuang@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Therapeutics.
Date: March 31, 2015.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Organelles' Dysfunction in Neurodegerative Disorders.
Date: March 31, 2015.
Time: 4:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Alessandra C. Rovescalli, Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205, MSC 7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; ''Program Project: BTRC Center Review''.
Date: March 31–April 2, 2015.
Time: 6:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.
Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301–435–2204, *girouxcn@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–14–015: Facile Methods and Technologies for Synthesis of Biomedically Relevant Carbohydrates.
Date: March 31, 2015.
Time: 12:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Kathryn M. Koeller, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–2681, *koellerk@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 27, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–05008 Filed 3–4–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0299]

Douglas M. Hargrave; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Dr. Douglas M. Hargrave (Dr. Hargrave), and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Dr. Hargrave for 2 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 Dr. Hargrave was convicted of a misdemeanor under Federal law for conduct relating to 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 Dr. Hargrave's debarment, FDA has considered the relevant factors listed in the FD&C Act. Dr. Hargrave 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 March 5, 2015.

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: Nathan Doty, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8556.

SUPPLEMENTARY INFORMATION:

I. Background

On August 11, 2009, in the U.S. District Court for the Northern District of New York, Dr. Hargrave, a physician, pled guilty to a misdemeanor under the FD&C Act, namely misbranding a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act (21 U.S.C. 331(k), 352(i)(3), 333(a)(1)) and 18 U.S.C. 2. The basis for this conviction was conduct surrounding his injection of patients seeking treatment with BOTOX/BOTOX Cosmetic (BOTOX) with a product, TRI-toxin, distributed by Toxin Research International, Inc. BOTOX is a biological product derived from Botulinum Toxin Type A that is manufactured by Allergan, Inc., and was approved by FDA for use on humans for the treatment of facial wrinkles in 1991. According to the records of the criminal proceedings, Dr. Hargrave's colleague in the same medical practice, The Plastic Surgery Group (TPSG), directed a nurse to obtain 31 vials of TRI-toxin, an unapproved drug product, which was represented by its distributor as ''Botulinum Toxin Type A.'' Dr. Hargrave then proceeded to inject approximately 25 patients, who believed they were being injected with BOTOX, with TRI-toxin as a substitute.

Dr. Hargrave 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 he

was convicted of a misdemeanor under Federal law 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 notice to Dr. Hargrave dated November 30, 2010, FDA's Office of Regulatory Affairs (ORA) proposed to debar him for 4 years from providing services in any capacity to a person having an approved or pending drug product application.

In a letter dated December 30, 2010, through counsel, Dr. Hargrave requested a hearing on the proposal. In his request for a hearing, Dr. Hargrave acknowledges his conviction under Federal law, as alleged by FDA. By letter dated January 28, 2011, Dr. Hargrave submitted materials and arguments in support of his request. Dr. Hargrave acknowledges that he was convicted of a Federal misdemeanor, as found in the proposal to debar, but argues that he should not be debarred for reasons related to the factual basis set forth in the proposal to debar. In particular, with respect to the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act, he argues that there are genuine and substantial issues of fact for resolution at a hearing, namely factual issues bearing on whether he participated in or even knew of certain conduct that resulted in his violation of the FD&C Act.

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 21 CFR 12.24(b)).

The Chief Scientist has considered Dr. Hargrave's arguments, as well as the proposal to debar itself, and concludes that, although Dr. Hargrave has failed to raise a genuine and substantial issue of fact requiring a hearing, the appropriate period of debarment is 2 years.

II. Arguments

In support of his hearing request, Dr. Hargrave first asserts that he is not subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act. He contends that he pled guilty to a misdemeanor violation of the FD&C Act (see section 303(a)(1) of the FD&C Act), which is a strict liability offense, and that thus there was no demonstration or admission of criminal intent or knowledge underlying the conviction. Dr. Hargrave concludes, therefore, that the conduct underlying his conviction did not undermine the process for the regulation of drugs.

Section 306(b)(2)(B)(i)(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 misdemeanor violations of the FD&C Act themselves are strict liability offenses, it stands to reason that criminal intent is not a critical component to debar an individual under section 306(b)(2)(B)(i)(I). During his criminal proceedings, Dr. Hargrave pled guilty to misbranding and causing the misbranding of a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act by offering an unapproved drug, TRI-toxin, for sale as an approved drug product, BOTOX. Dr. Hargrave's conduct undermined the process for the regulation of drugs in that it permitted an unapproved drug to be substituted for an approved drug without the knowledge of the patient. As a result, Dr. Hargrave is, in fact, subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

Dr. Hargrave next challenges the manner in which ORA applied the considerations under section 306(c)(3) of the FD&C Act in determining the appropriateness and period of his debarment. In the proposal to debar Dr. Hargrave, ORA stated that there are 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). ORA found with respect to Dr. Hargrave that the first two considerations weigh in favor of debarment and noted that the third and fourth considerations would be treated as favorable factors for him. In making all of its findings under section 306(c)(3) FD&C Act, ORA characterized Dr. Hargrave's conduct based on records from his criminal proceedings.

Under section 306(c)(3)(A) of the FD&C Act, in determining the appropriateness and period of debarment, FDA considers ''the nature and seriousness of the offense involved.'' In the proposal to debar, ORA relied on the criminal information to which Dr. Hargrave pled guilty to find that the conduct underlying his convictions:

> created a risk of injury to consumers due to the use of an unapproved drug, undermined [FDA's] oversight of an approved drug product by representing that [he] used the approved drug while actually substituting an unapproved drug in its place, and seriously undermined the integrity of [FDA's] regulation of drug products.

Under section 306(c)(3)(B) of the FD&C Act, ORA also considered the ''nature and extent of [Dr. Hargrave's] management participation in the offense'' and specifically found that he was a corporate principal who ''pleaded guilty to misbranding TRI-toxin'' and ''participated in the [TPSG's] unlawful conduct of administering [an] unapproved drug on multiple occasions to patients.'' ORA concluded, therefore, that the nature and seriousness of Dr. Hargrave's offenses and the nature and extent of management participation were unfavorable factors with respect to him.

Dr. Hargrave counters ORA's findings with respect to those two considerations in section 306(c)(3) of the FD&C Act with the following arguments: (1) That he did not admit any criminal intent or intentional wrongdoing when he pled guilty to a misdemeanor offense under the FD&C Act; (2) that, in fact, another physician at TPSG took unilateral action in ordering the TRI-toxin and directing a nurse to substitute it for BOTOX; (3) that the TRI-toxin vials that they used for injecting patients with TRI-toxin were identical to the vials he used for BOTOX before the substitution; and (4) that since the conviction for the underlying misdemeanor was of an individual, that there was no management participation and that, thus, the nature and extent of management participation is inapplicable as a factor in determining appropriateness and period of debarment. Dr. Hargrave concedes that he pled guilty to the misdemeanor offense because he was, in fact, guilty of offering TRI-toxin for sale to their patients as BOTOX. He argues, however, that the criminal records do not establish any intent or knowledge on his part and that thus the conduct underlying his conviction does not warrant debarment in light of the considerations in section 306(c)(3) of the FD&C Act.

As noted previously, ORA relied on the records of Dr. Hargrave's criminal proceedings for its findings in the proposal to debar. There is nothing definitive in the criminal records before FDA to contradict Dr. Hargrave's assertions with respect to the nature of his involvement in the misdemeanor offense to which he pled guilty. The criminal information to which Dr.

Hargrave pled guilty alleges that TPSG, as opposed to Dr. Hargrave, began ordering TRI-toxin for use in the medical practice, and there are no allegations that Dr. Hargrave took part in the ordering process. Indeed, the proposal to debar states that, as claimed by Dr. Hargrave, another physician in the practice, William F. DeLuca, Jr., was responsible for authorizing a nurse to substitute TRI-toxin for BOTOX, not Dr. Hargrave. At Dr. Hargrave's sentencing hearing, at which six other codefendants, including DeLuca, were also sentenced, the presiding judge also made clear that he believed DeLuca was the physician responsible for making the ''mistake'' that led to the other physician's offenses. In addressing DeLuca, the court stated:

> And we're here because of your actions and inactions. As I said, your mistakes were different in kind and degree from those of your colleagues. It was you who brought this drug into the practice, and it was your conduct and your failure to check out either the company or the drug that you were ordering, as you should have done, your negligence in doing that that has brought us here today in the end.

In addressing one of the other three physicians who pled guilty under circumstances similar to Dr. Hargrave's, the court further stated: ''There have been disputes on how in the past over who knew what and at what point in time. It is clear from the facts in this case that you had no knowledge that the substance was anything other than [BOTOX] until your discovery of it in November of 2004.''

In short, consistent with the proposal to debar Dr. Hargrave for 4 years, the records of his criminal proceedings establish that the misdemeanor convictions for the physicians in TPSG other than DeLuca were not based on any affirmative involvement in ordering the TRI-toxin or substituting the TRI-toxin for BOTOX. Furthermore, in proposing to debar Dr. Hargrave for 4 years, ORA did not rely on any findings with respect to Dr. Hargrave's intent or knowledge. Rather, citing the records of Dr. Hargrave's criminal proceedings, the proposal to debar simply rests on Dr. Hargrave's position of authority within TPSG and his conduct in misbranding TRI-toxin by administering it to patients who believed they were receiving BOTOX. As a result, under § 12.24(b), there is no genuine and substantial issue of fact raised by Dr. Hargrave's arguments for resolution at a hearing.

As set forth in the proposal to debar and summarized previously, Dr. Hargrave pled guilty to a misdemeanor under the FD&C Act for his role in offering a drug under the name of another. Based on the undisputed record before the Agency, the consideration in section 306(c)(3)(A) of the FD&C Act with respect to the nature and seriousness of the offense involved is a favorable factor. As reflected in the records of the criminal proceedings, Dr. Hargrave's offense did not rest on any intent or knowledge of wrongdoing on his part, nor may such intent or knowledge be inferred from the circumstances of his offense or the findings in the proposal to debar. Although, as a practicing physician, Dr. Hargrave should be expected to take the appropriate steps to avoid administering an unapproved new drug to patients or misrepresenting the drug being administered, his failure to do so over a t10-month period does not warrant considering the nature and seriousness of his offense as an unfavorable factor, relative to the range of conduct that might underlie a Federal misdemeanor conviction.

On the other hand, because of Dr. Hargrave's position of authority within TPSG and, thus, presumed ability to prevent the series of events that resulted in the offense underlying his misdemeanor conviction, the nature and extent of management participation in the offense is an unfavorable factor, for the purposes of the consideration under 306(c)(3)(B) of the FD&C Act. Dr. Hargrave asserts that there was no management participation, and that, thus, this factor is inapplicable because the underlying conviction was of an individual. However, the criminal information to which Dr. Hargrave pled guilty alleges that TPSG began ordering TRI-toxin for use in the medical practice. It is undisputed that Dr. Hargrave is a principal in TPSG, and this is the basis for considering the nature and extent of management participation as a factor in determining the appropriateness and period of debarment. FDA has relied on this factor in other debarment cases where the underlying conviction was of an individual (see 78 FR 68455 (November 14, 2013), 77 FR 27236–01 (May 9, 2012)).

The limited scope of his direct actions in committing the underlying misdemeanor offense does not mitigate the extent of his management participation, as established during his criminal proceedings and as set out in the proposal to debar. It is true that nothing in the criminal proceedings or the proposal to debar reflects any involvement by him in the decision to order the TRI-toxin and substitute it for BOTOX, and the proposal to debar specifically finds that another physician authorized a nurse to place that order. However, Dr. Hargrave, as a principal of TPSG, was responsible for failing to ensure that there were controls and procedures in place to prevent other physicians or a nurse from ordering unapproved drugs for administration to patients. His own admitted inaction on that front warrants treating his management participation as an unfavorable factor.[1]

Consistent with the proposal to debar, the record establishes that the medical practice of which Dr. Hargrave was a part ultimately took voluntary steps to mitigate the effect on the public health from its unlawful conduct (see section 306(c)(3)(C) of the FD&C Act). Furthermore, it is undisputed that Dr. Hargrave had no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F) of the FD&C Act). Therefore, these will be treated as favorable factors. In light of the foregoing four considerations, one of which weighs against Dr. Hargrave, debarment for 2 years is appropriate.

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 him, finds that Dr. Hargrave has been 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 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 2 years is appropriate.

As a result of the foregoing findings, Dr. Hargrave is debarred for 2 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**), (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 Dr. Hargrave, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. Hargrave, during his period of debarment, provides services in any capacity to a

[1] See *United States* v. *Park,* 421 U.S. 658, 673–74 (1975) (holding that a high-level manager within a business entity bears a responsibility to prevent and correct violations of the FD&C Act).

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. Hargrave during his period of debarment.

Any application by Dr. Hargrave for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2010–N–0299 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: February 24, 2015.

Stephen Ostroff,

Director, Office of the Chief Scientist.

[FR Doc. 2015–05046 Filed 3–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0586]

Clinical Trial Imaging Endpoint Process Standards; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Imaging Endpoint Process Standards.'' This guidance assists sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. This guidance focuses on imaging acquisition, display, archiving, and interpretation process standards that FDA regards as important when imaging is used to assess a trial's primary endpoint or a component of that endpoint. This draft guidance revises the draft guidance entitled ''Standards for Clinical Trial Imaging Endpoints'' issued on August 19, 2011.

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 May 4, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Louis Marzella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5406, Silver Spring, MD 20993–0002, 301–796–1414; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Imaging Endpoint Process Standards.'' The purpose of this guidance is to assist sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. It focuses on imaging acquisition, display, archiving, and interpretation standards that FDA regards as important when imaging is used to assess the trial's primary endpoint or a component of that endpoint. The guidance describes the minimum standards a sponsor should use to help ensure that clinical trial imaging data are obtained in a manner that complies with a trial's protocol, maintains imaging data quality, and provides a verifiable record of the imaging process.

This guidance addresses the background considerations for determining the role of imaging in a clinical trial as well as the major considerations in the development of an imaging charter that describes the trial's imaging methods. The guidance specifically addresses the technical components of a charter's description of the image acquisition, image interpretation, and image data development methods.

This draft guidance revises the draft guidance entitled ''Standards for Clinical Trial Imaging Endpoints'' issued on August 19, 2011 (76 FR 51993). Comments we received on the draft guidance have been considered and the guidance has been revised as follows: (1) It has been made clear that the guidance pertains to imaging in clinical trials intended to support approval of drugs and biological products and focuses upon standards that FDA regards as important when imaging is used to assess a trial's primary endpoint; (2) it has been made clear that the imaging charter can be either a single document or an ensemble of documents, depending on multiple factors; (3) it is emphasized that imaging risks are best described in the clinical protocol and should be addressed in consent documents instead of including this information in the imaging charter; (4) it has been emphasized that this guidance does not address whether imaging outcomes are clinically meaningful and are acceptable for drug approval evidence; (5) it has been noted that image acquisition phantoms may or may not be necessary, depending on the nature of the imaging in a clinical trial; (6) it has been modified to emphasize the need for the clinical protocol (not the charter) to describe how incidental findings will be handled; (7) it has been noted that the charter should identify any use of investigational equipment (for international trials, the guidance encourages use of equipment that is lawfully marketed in the area); and (8) a section has been added that describes the importance of having the clinical trial sponsor ensure the fidelity of all charter components with the clinical protocol.

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 major considerations for standardization of imaging primary endpoints in clinical trials of drugs and biological products. 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