regional transmission organizations.[1] Order No. 668 amended FERC Form Nos. 1 and 1–F by adding new schedules and revising existing schedules in the forms. The Commission updated the submission software used to file FERC Form Nos. 1 and 1–F to reflect the new financial reporting requirements of Order No. 668.

The annual filing date for FERC Form Nos. 1 and 1–F is April 18. However, in light of the software changes made to implement Order No. 668, the filing deadline for the 2006 FERC Form Nos. 1 and 1–F is extended until May 18, 2007.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6511 Filed 4–6–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 2003F–0088 (formerly 03F–0088)]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of requests for a hearing.

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying requests that it has received for a hearing on the final rule that amended the food additive regulations by establishing a new maximum permitted energy level of x-rays for treating food of 7.5 million electron volts (MeV) provided that the x-rays are generated from machine sources that use tantalum or gold as the target material, with no change in the maximum permitted dose levels or uses currently permitted by FDA's food additive regulations. After reviewing the objections to the final rule and the requests for a hearing, the agency has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for removing the amendment to the regulation.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA published a notice in the **Federal Register** of March 13, 2003 (68 FR 12087), announcing the filing of food additive petition, FAP 3M4745, by Ion Beam Applications to amend the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) by increasing the maximum permitted energy level of x-rays for treating food from 5 to 7.5 MeV. The rights to this petition were subsequently transferred to Sterigenics International, Inc. In response to this petition, FDA issued a final rule in the **Federal Register** of December 23, 2004 (69 FR 76844) permitting the safe use of 7.5 MeV x-rays for treating food provided that the x-rays are generated from machine sources that use tantalum or gold as the target material, with no change in the maximum permitted dose levels or uses currently permitted by FDA's food additive regulations (the 7.5 MeV x-ray final rule). The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by January 24, 2005).

II. Objections and Requests for a Hearing

Section 409(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(f)) provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, specifying with particularity the provisions of the order ''deemed objectionable, stating reasonable grounds therefore, and requesting a public hearing upon such objections.'' FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing (*Community Nutrition Institute* v. *Young*, 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986)).

Under the food additive regulations at 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the 7.5 MeV x-ray final rule, FDA received about 100 objections within the 30-day objection period. All but one of these submissions expressed general opposition to increasing the maximum permitted energy level of x-rays used to irradiate food and to food irradiation. Most of these objections were form letters, identically worded, urging FDA to conduct additional studies on the effects of 7.5 MeV x-rays on food and objecting ''to the agency's decision knowing that some amount of radioactivity could be created in food treated with 7.5 MeV.'' While most of these objections requested a hearing, no evidence was submitted in support of these objections that could be considered in an evidentiary hearing. These submissions expressing general opposition raise no factual issue for resolution and, therefore, do not justify a hearing.[1] The one submission raising specific objections was a letter from Public Citizen with six objections to the 7.5 MeV x-ray final rule. The letter requested a hearing on issues raised by each objection. These objections are addressed in section IV of this document.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and

[1] *Accounting and Financial Reporting for Public Utilities Including RTOs,* Order No. 668, FERC Stats. & Regs. ¶ 31,199 (2005), *reh'g denied,* Order No. 668–A, FERC Stats. & Regs. ¶ 31,215 (2006), *reh'g denied,* 117 FERC ¶ 61,066 (2006).

[1] A large number of these form letters were submitted after the close of the objection period. Tardy objections fail to satisfy the requirements of 21 U.S.C. 348(f)(1) and need not be considered by the agency (*ICMAD* v. *HEW*, 574 F.2d 553, 558 n.8 (D.C. Cir), *cert. denied*, 439 U.S. 893 (1978)).

contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the act or any FDA regulation; and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20, §§ 12.21, and 12.22, and in the notice issuing the final regulation or the notice of opportunity for hearing are met.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), *reh. denied*, 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (see § 12.28).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held (*Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir.1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960)). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information (see *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971)). In other words, a hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue'' (*Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977)). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles ''self evidently'' ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: ''The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.'' *Retail Clerks Union, Local 1401* v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See *Costle* v. *Pacific Legal Foundation*, supra at 215–220. See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1968), *cert. denied*, 393 U.S. 1093 (1969).))

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

IV. Analysis of Objections and Response to Hearing Requests

The letter from Public Citizen raises six issues that they believe to be factual and requests a hearing based on these objections. FDA addresses each of the objections in the following paragraphs, as well as the evidence and information filed in support of each, comparing each objection and the information submitted in support of it to the standards for granting a hearing in § 12.24.

(1) Public Citizen contends that FDA did not adequately account for the fact that an electron beam on an x-ray target is not monoenergetic, and that a significant portion of the beam may be higher than the nominal energy, resulting in higher neutron production in the food and more activity. Public Citizen cites a published paper in the petition in which the authors note that measurements and calculations of a 7.5 MeV setting actually correspond to 8.1 MeV 0.8 MeV.

The objection does not raise a genuine and substantial issue of fact for resolution at a hearing. Contrary to the objection, the final rule does not set a ''nominal energy'' limit. The final rule sets out 7.5 MeV as the maximum energy permitted. X-rays from machine sources at energies exceeding 7.5 MeV are not permitted by the final rule.

Further, the objection provides no evidence to support the contention that safety concerns regarding inherent limitations on the precision of setting and measuring voltage were not considered. The paper referred to in the objection, Gregoire, O., Cleland, M.L., Wakeford, Mittendorfer, et al., ''Radiological Safety of Food Irradiation With High Energy X-Rays: Theoretical Expectations and Experimental Evidence,'' 2002, was included as a reference in the final rule and counters the objection. The paper discusses the radiological implications of irradiating meat with 7.5 MeV x-rays to an x-ray dose of 15 kGy, which is more than twice the maximum dose allowed for meat irradiation (4.5 kGy maximum for refrigerated meat and 7.0 kGy maximum for frozen meat) (see § 179.26(b)). Experiments were performed with x-ray machines that use two different types of electron accelerators, one delivering electrons with a narrow electron energy spread, the other delivering a broad energy spread. The Gregoire paper concluded that risk to individuals from intake of food irradiated with x-rays from 7.5 MeV electrons, even with a broad energy spread, would be trivial.

In the experiments discussed in the Gregoire paper, the equipment was set to achieve a voltage of 7.5 MeV. Measurements (including calculations) to verify the precision of the settings estimated that the machine produced electrons at an energy of approximately 8.1 MeV, with an uncertainty margin of 0.8 MeV. In other words, within the limits of precision of the measurements, the energy of the electrons used to produce the x-rays was shown to be greater than 7.3 MeV but less than 8.9 MeV. FDA notes that even though the equipment in this experiment produced a higher energy level than permitted by the regulation, the results show that any radioactivity that might be induced at that higher energy level is trivially small.

Public Citizen has not raised a genuine and substantial issue of fact and

has not provided any information that contradicts the agency's safety determination. Thus, a hearing is not justified based on this objection (§ 12.24(b)(1) and (2)).

(2) Public Citizen claims that FDA has concluded that any induced activity in food from treating it with 7.5 MeV x-rays is safe without a standard for a ''safe'' level of induced activity in food and further objects to any additional radiation level in treated food.

The objection does not cite any support for its contention that FDA must establish a general standard for a safe level of induced activity in food beyond the act's requirements for food additive approvals. The use of x-rays to treat food is a food additive under the act's definition of ''food additive,'' which includes any source of radiation intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food (section 201(s) of the act) (21 U.S.C. 321(s)). Section 409 of the act requires that a regulation approving a food additive must prescribe, with respect to the proposed uses of the additive, the conditions under which the additive may be safely used. Further, section 409 of the act sets out that no such regulation can issue if a fair evaluation of the data fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. FDA has defined ''safe'' and ''safety'' by regulation to mean that ''there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.'' (21 CFR 170.3(i)).

In accordance with the requirements of section 409 of the act and the food additive regulations, FDA determined that food treated with 7.5 MeV x-rays is safe by comparing the total annual dose from eating irradiated foods with the annual dose from naturally occurring radionuclides in the food. FDA's determination was based on its review of the data in the record, including the reports referenced in the final rule from the International Atomic Energy Agency, Gregoire et al., and the independent evaluation of the data by Oak Ridge National Laboratory. FDA concluded based on these analyses that any radioactivity that may be induced in any food treated with 7.5 MeV x-rays will be trivially low and that any potential human exposure due to consumption of irradiated food will be inconsequential compared to that from radionuclides that are present naturally in food.

Public Citizen's objection presents no factual evidence that FDA has overlooked in reaching the decision that 7.5 MeV x-rays are safe for treating food under the conditions of use specified in the regulation. Thus, Public Citizen has failed to justify a hearing on this issue (§ 12.24(b)(2)).

(3) Public Citizen objects to the agency's approval of 7.5 MeV x-rays for treating food without assessing the risk of getting cancer from eating food with added radioactivity. The objection points to a paper by Ari Brynjolfsson, cited by the petitioner, which estimates the lifetime cancer risk from eating foods irradiated with 7.5 MeV x-rays to be 0.8 per million.[2]

FDA disagrees with Public Citizen's assertion that it did not consider the risk of getting cancer from eating food treated with 7.5 MeV x-rays during its review of FAP 3M4745. As stated in the preamble of the rule, FDA contracted with Oak Ridge National Laboratory (ORNL) to perform an independent evaluation of the data in the administrative record, including an evaluation of cancer risk. The ORNL evaluation was placed in the docket when the rule published. ORNL concluded that because the factors used in the data in the administrative record to estimate cancer risk are based on much higher doses than permitted in the rule, the data in the administrative record, including the data in the Brynjolfsson paper, cannot be applied with any credibility to extrapolate cancer risk to the extremely low potential doses that a person might receive from consuming food treated with 7.5 MeV x-rays. The extrapolations that would be required would yield estimated risks far too small to reliably measure or verify. FDA agrees with this conclusion.

The only evidence referenced by Public Citizen in support of its assertion is the Brynjolfsson paper, which was part of the administrative record and was considered in ORNL's evaluation of the data and FDA's safety determination. Therefore, Public Citizen has not identified any evidence to support its assertion that was not already considered by FDA in its safety determination. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (21 CFR 12.24(b)(2)).

(4) Public Citizen asserts that FDA did not comply with § 170.22 (21 CFR 170.22), which states that a food additive will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals unless evidence is submitted which justifies use of a different safety factor. Public Citizen expresses the view that this non-compliance includes not only the failure to conduct any animal experiments using foods irradiated with 7.5 MeV x-rays, but also the failure to calculate a 100-to-1 safety factor or submit evidence that justifies the use of a different safety factor.

The objection does not include any evidence or support for the contention that animal experiments are required to be conducted to determine whether a proposed use of a food additive is safe. The safety criteria that must be considered by the agency before a food additive regulation is issued are listed in 21 U.S.C. 348(c)(5). The act does not prescribe what safety tests should be performed to determine whether an additive is safe. Public Citizen's objection references the regulation in § 170.22 which sets out a safety factor of 100-to-1 in applying animal experimentation data to man (that is, the additive will not be approved for use in an amount greater than 1/100th of the maximum amount demonstrated to be without harm to experimental animals), unless evidence is submitted which justifies use of a difference safety factor. That regulation concerns how to apply animal experimentation data when it exists. It does not, however, require that animal testing be done in all food additive safety determinations.

Because of the extremely low levels of induced radioactivity in food from the use of 7.5 MeV x-rays, it would not be possible to measure any toxicological effects from this induced activity in food fed to animals even with the most sensitive toxicological testing. Consequently, animal testing is neither necessary nor helpful to demonstrate the safety of food treated with 7.5 MeV x-rays. Rather, safety was demonstrated by showing that calculated estimates of radiation exposure from induced activity in food from the use of 7.5 MeV x-rays is far below the exposure from activity resulting from radionuclides that are present naturally in food. FDA concluded that such an analysis provides information that is far more sensitive to potential effects than can be obtained from the use of animal studies. Public Citizen has submitted no information to establish that the animal and other testing it recommended is required to demonstrate safety, or even that such testing would be valid to assess safety. Because Public Citizen provided no evidence to consider in

[2] Public Citizen incorrectly states in their objection that the cancer risk estimated by the author is 0.08 per million.

support of its assertion, FDA is denying the request for a hearing on this point because a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (21 CFR 12.24(b)(2)).

(5) Public Citizen asserts that by FDA failing to comply with § 170.22, FDA did not comply with § 170.20 (21 CFR 170.20), which states that ''the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences National Research Council.''

Section 170.22 pertains to safety factors to be applied to animal experimentation data in determining whether a proposed use of a food additive is safe. As discussed previously in item 4, no animal studies were necessary nor were any conducted to demonstrate that the use of 7.5 MeV x-rays is safe for treating food. Because the provisions of § 170.22 do not apply to the agency's review of FAP 3M4745, Public Citizen's assertion that FDA did not comply with § 170.20 because it did not comply with § 170.22 is without merit. Therefore, this objection is not a basis for a hearing because there is no genuine and substantial issue of fact for resolution (§ 12.24(b)(1)).

(6) Public Citizen asserts that FDA did not comply with 21 U.S.C. 348(c)(3)(A), which states that ''No such regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man.'' Nor has FDA complied with § 170.3(i), which defines ''safe'' as ''there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

Public Citizen has not provided any evidence to support these allegations or that contradicts or challenges the agency's safety determination. The agency finds that this objection is merely a general description of Public Citizen's position, and that it does not raise a factual issue for resolution at a hearing. Therefore, FDA is denying the requests for a hearing on this point because there is no genuine and substantial issue of fact for resolution at a hearing, and a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(1) and (b)(2)).

V. Summary and Conclusions

Section 409 of the act requires that a food additive be shown to be safe prior to marketing. Under § 170.3(i), a food additive is ''safe'' if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the final rule approving the use of 7.5 MeV x-rays for treating food, FDA concluded, based on its evaluation of the data submitted in the petition and other relevant material, that the use of 7.5 MeV x-rays proposed in the petition for treating food is safe under the conditions set forth in the regulation codified at § 179.26. The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. Once FDA makes a finding of safety, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co.* v. *FDA*, 606 F.2d 1307, 1314–1315 (D.C. Cir. 1979)).

None of the objections received contained evidence to support a genuine and substantial issue of fact. Nor has any objector established that the agency overlooked significant information in reaching its conclusion. Therefore, the agency has determined that the objections that requested a hearing do not raise any substantial issue of fact that would justify an evidentiary hearing (§ 12.24(b)). Accordingly, FDA is not making any changes in response to the objections and is denying the requests for a hearing.

Dated: March 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6646 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020

[Docket No. 2007N–0104]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct typographical errors and to ensure accuracy and clarity in the agency's regulations.

EFFECTIVE DATE: April 9, 2007.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2343.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020 to correct typographical errors, and update addresses, telephone numbers, and wording to ensure accuracy and clarity in the agencies medical device regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these errors are nonsubstantive.

I. Highlights of the Final Rule

FDA is making changes to correct typographical and other minor errors in certain device regulations in parts 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020 (21 CFR 803, 814, 820, 821, 822, 874, 886, 1002, 1005, and 1020).

1. FDA is revising § 803.11 and replacing ''301–443–8818'' with ''240–276–3151.''

2. FDA is revising § 803.11 and replacing ''*http://www.fda.gov/cdrh/mdr/mdr-forms.html*'' with ''*http://www.fda.gov/medwatch/getforms.htm.*''

3. FDA is revising § 803.21(a) and replacing ''301–443–8818'' with ''240–276–3151.''

4. FDA is revising § 803.21(a) and replacing ''*http://www.fda.gov/cdrh/mdr/373.html*'' with ''*http://www.fda.gov/cdrh/mdr/mdr-forms.html.*''

5. FDA is revising § 814.20(g) and replacing ''FDA has issued a PMA guidance document to assist the applicant in the arrangement and content of a PMA. This guidance document is available on the Internet at *http://www.fda.gov/cdrh/dsma/pmaman/front.html.* This guidance document is also available upon request from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, FAX 301–443–8818'' with ''Additional information on FDA policies and procedures, as well as links to PMA guidance documents, is available on the Internet at *http://www.fda.gov/cdrh/devadvice/pma/.*''

6. FDA is revising § 820.1(e) and replacing ''Division of Small