

after the first day of the first quarter after applicable regulatory approval. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

By the Commission.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-6739 Filed 3-22-11; 8:45 am]

BILLING CODE 6717-01-P

DELAWARE RIVER BASIN COMMISSION

18 CFR Part 410

Amendments to the Water Quality Regulations, Water Code and Comprehensive Plan To Update Water Quality Criteria for Toxic Pollutants in the Delaware Estuary and Extend These Criteria to Delaware Bay

AGENCY: Delaware River Basin Commission.

ACTION: Final rule.

SUMMARY: By Resolution No. 2010-13 on December 8, 2010, the Delaware River Basin Commission (DRBC or "Commission") approved amendments to its Water Quality Regulations, Water Code and Comprehensive Plan to update the Commission's human health and aquatic life stream quality objectives (also called water quality criteria) for toxic pollutants in the Delaware Estuary (DRBC Water Quality Zones 2 through 5) and extended application of the criteria to Delaware Bay (DRBC Water Quality Zone 6).

DATES: *Effective Date:* March 23, 2011. The incorporation by reference of the publications listed in this rule is approved by the Director of the Federal Register as of March 23, 2011.

FOR FURTHER INFORMATION CONTACT: For questions about the technical basis for the rule, please contact Dr. Ronald MacGillivray at 609-477-7252.

SUPPLEMENTARY INFORMATION: The Delaware River Basin Commission is a federal-state regional agency charged with managing the water resources of the Delaware River Basin without regard to political boundaries. Its members are the governors of the four basin states—Delaware, New Jersey, New York, and Pennsylvania—and the North Atlantic Division Commander of the U.S. Army Corps of Engineers, representing the Federal government.

Notice of the proposed amendments appeared in the **Federal Register** (75 FR 41106) on July 15, 2010 as well as in the Delaware Register of Regulations (14 DE Reg. 70-83 (08/01/2010)) on August 1, 2010, the New Jersey Register (42 N.J.R. 1701(a)) on August 4, 2010, the New York State Register (p. 6) on July 21, 2010 and the Pennsylvania Bulletin (40 Pa. B. 4208) on July 31, 2010. A public hearing was held on September 23, 2010 and written comments were accepted through October 1, 2010. The commission received two written submissions and no oral testimony on the proposed changes. The Commission made minor revisions to the proposed amendments in response to the comments received. A comment and response document setting forth the Commission's responses and revisions in detail was approved by the Commission simultaneously with adoption of the final rule.

Resolution No. 2010-13, the text of the final rule, a copy of the comment and response document, and a basis and background document published simultaneously with the proposed rule are available on the Commission's Web site, at http://www.state.nj.us/drbc/toxics_info.htm.

List of Subjects in 18 CFR Part 410

Incorporation by reference, Water audit, Water pollution control, Water reservoirs, Water supply, Watersheds.

For the reasons set forth in the preamble, the Delaware River Basin Commission amends part 410 of title 18 of the Code of Federal Regulations as follows:

PART 410—BASIN REGULATIONS; WATER CODE AND ADMINISTRATIVE MANUAL—PART III WATER QUALITY REGULATIONS

- 1. The authority citation for part 410 continues to read as follows:

Authority: Delaware River Basin Compact, 75 Stat. 688.

- 2. Amend § 410.1 by revising the first sentence of paragraph (c) to read as follows:

§ 410.1 Basin regulations—Water Code and Administrative Manual—Part III Water Quality Regulations.

* * * * *

(c) Work, services, activities and facilities affecting the conservation, utilization, control, development or management of water resources within the Delaware River Basin are subject to regulations contained within the Delaware River Basin Water Code with Amendments Through December 8, 2010 and the Administrative Manual—

Part III Water Quality Regulations with Amendments Through December 8, 2010. * * *

Dated: March 15, 2011.

Pamela M. Bush,
Commission Secretary.

[FR Doc. 2011-6636 Filed 3-22-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2002-F-0198] (formerly Docket No. 2002F-0316)

Food Additives Permitted for Direct Addition to Food for Human Consumption; Bacteriophage Preparation

AGENCY: Food and Drug Administration, HHS.

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

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 to provide for the use of a bacteriophage preparation as an antimicrobial agent against *Listeria monocytogenes* on ready-to-eat (RTE) meat and poultry products. 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 revoking the amendment to the regulation. FDA also is denying the request for a stay of the effective date of the final rule.

DATES: Effective date of the final rule published in the **Federal Register** of August 18, 2006 (71 FR 47729) confirmed: August 18, 2006.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1303.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA published a notice in the **Federal Register** of July 22, 2002 (67 FR 47823), announcing the filing of food additive petition, FAP 2A4738, by Intralytix Inc., to amend the food additive regulations by providing for the safe use of a

mixture of bacteriophages as an antimicrobial agent against *L. monocytogenes* on foods, including fresh meat products, fresh poultry, and poultry products. On December 18, 2003, the petitioner amended the petition to limit the petitioned use only to RTE meat and poultry products. In response to this petition, FDA issued a final rule in the **Federal Register** of August 18, 2006 (71 FR 47729), approving the use of the bacteriophage preparation on RTE meat and poultry products. This rule will be referred to in this document as the “bacteriophage 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 September 18, 2006).

II. Objections, Requests for a Hearing, and Request for a Stay of Effective Date

Section 409(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 therefor, 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 (DC 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 bacteriophage final rule, FDA received more than 70 objections within the 30-

day objection period. All but one of these submissions expressed general opposition to the use of the bacteriophage preparation on RTE meat and poultry products; however, no evidence was submitted in support of these objections. As stated previously, under section 409(f)(1) of the FD&C Act, objections must “[specify] with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor * * *.” These submissions did not provide reasonable grounds and identified no substantive issue to which the Agency can respond. Therefore, these submissions are denied and will not be considered further. The submission raising specific objections was a letter from Food & Water Watch (FWW) with six objections. The FWW letter sought a revocation of the bacteriophage final rule and requested a hearing on the issues raised by each objection. The letter also requested that the regulation be stayed pending a public hearing of the scientific issues. 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 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 requester; 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 FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, *e.g.*, 21 CFR 10.20 and §§ 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. U.S. Environmental Protection Agency*, 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 Association 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 & Chemicals, Inc. v. Flemming*, 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960)). 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. Consumer Product Safety Commission*, 555 F.2d 677, 684 (9th Cir. 1977)). A hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County, Inc. v. Federal Power Commission*, 414 F.2d 1125, 1128–29 and n.5 (D.C. Cir. 1969); *Sun Oil Co. v. Federal Power Commission*, 256 F.2d 233, 240–41 (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 cannot raise 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 one fair opportunity.” *Retail Clerks Union, Local 1401 v. National Labor Relations Board*, 463 F.2d 316, 322 (DC 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 (DC 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 FWW submission raises six objections based on 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.

A. FWW's Assertion That FDA Failed To Follow Its Own Guidelines

FWW claims that FDA failed to follow its own guidelines for assessing the safety of food additives. Specifically, FWW states that FDA did not “certify” that it followed the procedures stated in current publications of the National Academy of Sciences/National Research Council (NAS/NRC) when reviewing the bacteriophage petition, or if different procedures were used, FDA did not “certify” that they are as reliable as the NAS/NRC procedures, as FWW states is required by § 170.20 (21 CFR 170.20). FWW also contends that FDA did not comply with the testing set forth in its own guidance entitled “Toxicological Principles for the Safety Assessment of Food Ingredients,” otherwise known as FDA’s Redbook, or establish a 100-fold safety factor for the additive as set forth in 21 CFR 170.22. If a different safety factor was used, FWW asserts that FDA did not provide evidence to justify a different safety factor. FWW also questions the relevance and applicability of the various studies relied on by the petitioner to show safety because of either: (1) Deficiencies

with how the studies were conducted, (2) the studies investigated efficacy rather than safety, or (3) the substance tested is not the same bacteriophage that is the subject of the petition.

Contrary to what FWW appears to assert, FDA notes that the Agency does not “certify” that the procedures used in evaluating a food additive petition either followed the current NAS/NRC procedures or were as reliable as those procedures. Section 170.20 sets forth the general scientific principles that FDA uses in evaluating a food additive petition and cites the principles and procedures stated in current publications of the NAS/NRC as a guide that the Agency uses in its safety evaluations of food additives. Nevertheless, FDA has consistently taken the position that many scientifically valid types of data may properly support a finding that the proposed use of a food additive will cause “no harm” to consumers. Moreover, § 170.20(a) specifically states that “A petition will not be denied, however, by reason of the petitioner’s having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures.” Similarly, NAS/NRC acknowledges in the conclusions of its document regarding procedures for evaluating the safety of food chemicals that the document’s purpose is to “guide and stimulate—not replace—informed professional and administrative judgment” (Ref. 1).

FDA did not request the petitioner to carry out studies recommended in NAS/NRC guidelines because the bacteriophages that are the active component of the food additive infect *L. monocytogenes* exclusively, and not mammalian cells. (See discussion at 71 FR 47729 at 47730). As such, traditional animal testing of the additive as recommended by NAS/NRC for food chemicals, is neither necessary nor helpful to demonstrate that the petitioned use of the additive is safe.

Regarding the use of safety factors, the use of a safety factor is intended to account for the uncertainty of extrapolating animal toxicity data to humans. Because bacteriophages do not infect mammals, the use of a safety factor is unnecessary to provide adequate assurance of safety.

Similarly, due to the nature of this food additive, there is no need to assign a concern level as set forth in the Redbook. FDA’s Redbook provides

guidance that represents the Agency’s current thinking on the information needed for the safety assessment of food ingredients. As with any Agency guidance, the Redbook does not bind the petitioner or the Agency to follow specific procedures that are recommended. Alternative approaches are permissible if such approaches satisfy the requirement of the applicable statute and regulations. Importantly, the statute does not prescribe the safety tests to be performed but leaves that determination to the discretion and scientific expertise of FDA. Not all food additives require the same amount or type of testing. The testing and data necessary to establish the safety of an additive will vary depending on the type and characteristics of a particular additive and its intended use. Concern levels are used to determine the recommended toxicity tests for an additive. It was unnecessary to assign a concern level in the present case, because FDA’s primary concern about the subject additive was the safety of potential residual components from the host organism, *L. monocytogenes*, and not the bacteriophages themselves.

One such residue of concern was Listeriolysin O (LLO), an exotoxin produced by the host organism. To address this concern, the petitioner analyzed the bacteriophage preparation for LLO and was unable to detect it using a method sensitive to 5 hemolytic units per milliliter (HU/ml). Even when the food additive was concentrated 10-fold, the petitioner still did not detect any hemolytic activity. Although LLO was not detected in the bacteriophage preparation, FDA established a specification of 5 HU/ml for the maximum amount of LLO permitted in the bacteriophage preparation as a condition of safe use, which is the limit of detection for the method provided by the petitioner. FDA concluded that the potential residues of LLO that may be found in the food additive are negligible (*i.e.*, 5 HU/ml or less) and do not pose a safety concern for the use of the food additive as an antimicrobial agent on RTE meat and poultry products. Furthermore, as discussed in the bacteriophage final rule, the presence of any small amount of LLO in the bacteriophage preparation may be mitigated by the following factors: Inactivation of LLO by cholesterol that is present in RTE meat and poultry products; inactivation of LLO by the low stomach pH; and inactivation of orally consumed LLO by human defense mechanisms (*e.g.*, normal intestinal microflora and cell-mediated immunity reactions) and degradation by

proteolytic enzymes in the diet or in the stomach. FDA concluded that reliable alternative methods from NRC/NAS procedures were used to establish the safety of the bacteriophage preparation for its use on RTE meat and poultry products, and that the data considered for this regulation, when evaluated in its entirety, are sufficient to support the safety of the bacteriophage preparation for that use.

FWW's submission provides no evidence that FDA failed to follow its own guidelines for assessing the safety of food additives. The FWW submission does not raise a genuine and substantial issue of fact and does not provide any specifically identified reliable evidence that, if established at a hearing, would be adequate to demonstrate that FDA acted in violation of its governing statutes and regulations. Thus, a hearing is not justified based on this objection (§ 12.24(b)(1), (b)(2), and (b)(3)).

B. Inactivation of LLO By Stomach Acid and Cholesterol

FWW contends that FDA relies on conjecture in concluding that foods treated with a bacteriophage preparation are safe for human consumption. Specifically, FWW asserts that FDA's conclusion that any residual LLO will be inactivated by factors such as cholesterol in the meat or poultry, acidity within the stomach, and proteolytic enzymes present in the food or in the stomach is based on unsupported assumptions and not experimental data. Regarding the inactivation of LLO by cholesterol, FWW's asserts that FDA's conclusion about mitigation of LLO by cholesterol was not based on any data on the levels of cholesterol in meat necessary to inactivate LLO, and that the mechanism for the inactivation of LLO by cholesterol is "not yet fully understood by researchers." FWW also states that there is a need for a more thorough study to investigate the reaction of certain sensitive population groups to this bacteriophage preparation.

As stated in the bacteriophage final rule, the toxicity of LLO has been shown to be significantly reduced—by as much as 200- to 2,000-fold—following pre-incubation of LLO with added cholesterol *in vitro*, based on results of a study conducted by Jacobs et al (Ref. 2). The results showed that there is almost no hemolytic if LLO is pretreated with cholesterol at 1 milligram/100 grams (mg/100g). It is well established that there are relatively high concentrations of cholesterol in RTE meat and poultry products (approximately 38 to 156 mg/100 g (Ref. 3)). Therefore, since the bacteriophage

preparation is to be used on RTE meat and poultry products, and these products contain significant amounts of cholesterol, the findings from Jacobs et al. directly support FDA's conclusion about inactivation of LLO by cholesterol in RTE meat and poultry products. While the mechanism by which added cholesterol inhibits LLO may not be fully understood, that does not undermine the evidence that supports the Agency's conclusion.

Regarding inactivation of LLO by acidity, the data considered by FDA in its review of the petition indicate that LLO has activity only within a pH range between 4.9 and 8 while losing activity at a pH outside this range, especially in very acidic (low pH) or very alkaline (high pH) environments. Since the pH inside the stomach is normally between 1.0 and 3.5 (Ref. 4), the acidic environment in the stomach would be a defense against any residual LLO from the use of the additive. No data were submitted by FWW to the contrary, nor was any information provided that would justify the need for studies to investigate the reaction of certain sensitive population groups to the bacteriophage preparation. Because FWW provided no evidence to support these contentions, FDA is denying the request for a hearing on these issues; a hearing will not be granted on the basis of mere allegations or denials or general positions and contentions (§ 12.24(b)(2)).

C. FWW's Contention That Petitioner's Efficacy Studies Are Inadequate

FWW contends that the results of the efficacy studies for the bacteriophage preparation submitted by the petitioner are inadequate to show that the preparation will sufficiently control *L. monocytogenes* in RTE meat and poultry products. In addition, FWW points out that some other methods for killing bacteria achieve a greater log reduction of bacteria than the bacteriophage preparation.

During its evaluation of FAP 2A4738, FDA consulted with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), consistent with 21 CFR 171.1(n) and with a memorandum of understanding (MOU) between the two Agencies for reviewing the safety of substances used in the production of meat and poultry products. Under the MOU, FDA is responsible for reviewing an ingredient's safety, and USDA/FSIS is responsible for evaluating its suitability. (MOU 225-00-2000; see also 65 FR 51758 at 51759, August 25, 2000). Suitability relates to the effectiveness of the ingredient in performing the

intended purpose of use and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers. As we stated in the bacteriophage final rule, "FDA recognizes that there may be meat or poultry products considered RTE for which use of the additive may not be suitable within the meaning of those statutes. This regulation addresses only the safety standard under section 409 of the Federal Food, Drug, and Cosmetic Act and does not address requirements for suitability administered by the USDA." (71 FR 47729 at 47731). FSIS concurred with the issuance of FDA's final rule.

FDA is denying the request for a hearing on this point because a hearing will not be granted unless there is a genuine and substantial factual issue to be resolved (§ 12.24(b)(1)), and resolution of the factual issue in the way sought is adequate to justify the action requested (§ 12.24(b)(4)).

D. FWW's Assertion That Key Research Used to Support the Rule Has Not Been Published in Peer-Reviewed Journals

FWW asserts that key research submitted by the petitioner in support of their additive was not published in peer-reviewed journals, which they claim is required under § 170.31(i) (21 CFR 170.3(i)). Specifically, FWW is referring to the definition of safe or safety which is defined in § 170.3(i) as " * * * a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. * * * "

FWW has misinterpreted § 170.3(i). This regulation does not require that in order to establish safety, the research submitted by a petitioner in support of a food additive must be published in a peer-reviewed journal. This regulation states that "Safety may be determined by scientific procedures or by general recognition of safety." Importantly, scientific procedures are defined under § 170.3(h) as " * * * human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Therefore, FDA does not require the key research submitted by a petitioner in support of a food additive be published in a peer-reviewed journal to establish safety. This objection does not raise a genuine and substantial issue of fact for resolution at a hearing. FDA is denying the request for a hearing on this point because a hearing will not be granted if there is no genuine and substantial factual issue to be resolved (§ 12.24(b)(1)).

E. FWW's Contention That FDA Did Not Adhere to Its Requirements on Making Information Publicly Available

FWW contends that the Agency did not follow the requirements in § 171.1(h) (21 CFR 171.1(h)) for making information publicly available. They cite § 171.1(h)(1), which states: "The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the Federal Register * * *." FWW states that FDA did not publicly disclose the releasable information from FAP 2A4738 after the notice of filing of the petition published in the **Federal Register** as required under § 171(h)(1). FWW also states "as of the submission of these objections, FDA has still not made much of this information, including much of this petition, available."

FWW misinterprets § 171.1(h)(1). That paragraph does not mean that the releasable data and information in a petition are publicly disclosed when the notice of filing publishes, but merely that the information in the petition is available for public disclosure. Before the information in a petition is actually disclosed, the Agency has to purge all data and information that are protected from disclosure. Because this is a labor intensive process, FDA does not preemptively disclose the information in a petition at this time, but rather releases it in response to requests made under the Freedom of Information Act (FOIA). To disclose the information in a petition before a request is received would not be an efficient use of Agency resources.

In the case of FAP 2A4738, the notice of filing was published in the **Federal Register** of July 22, 2002, at which time the releasable information in the petition was available for public disclosure through the Agency's FOIA process. The final rule for this petition published in the **Federal Register** of August 18, 2006, and the period for submitting objections to this rule ended on September 18, 2006. Prior to the beginning of the objection period, FDA had not processed any FOIA requests for this information. The petition therefore had not been previously redacted.

On September 7, 2006, arrangements were made for FWW to go to FDA's offices to review the petition, including specific sections in which the organization had expressed a particular interest. On September 8, 2006, FWW came to FDA's offices and reviewed releasable parts of the petition. At the end of their visit, FWW left with

approximately 250 pages of documents. In addition, an FOIA request from Wenonah Hauter of FWW (dated August 31, 2006 and received and logged by FDA's Freedom of Information Staff on September 5, 2006) was processed, and the information sent to FWW on February 9, 2007.

The objection provides no evidence to support the contention that FDA did not follow § 171.1(h) regarding releasable information from FAP 2A4738. FDA is denying the request for a hearing on this point because a hearing will not be granted if there is no genuine and substantial factual issue to be resolved (§ 12.24(b)(1)).

F. FWW's Contention That FDA Did Not Provide Adequate and Timely Notice of the Standards Used To Evaluate the Petition

FWW contends that FDA did not provide timely notice of the standards it used for evaluating the petition and how the data justifies the Agency's conclusion. Specifically, FWW contends that FDA made available the memoranda referenced in the bacteriophage final rule and select portions of the petition only after much pleading on the 13th and 21st day, respectively, after the start of the statutorily required 30-day objection period.

On August 17, 2006, the date the bacteriophage final rule was placed on public display and 1 day before the rule published in the **Federal Register**, the four references cited in the final rule were also placed on public display in the petition docket. However, after realizing that some of the references contained confidential information, FDA immediately removed them from the docket to redact any confidential information. The redacted references were placed back in the docket on August 31, 2006.

The Agency was first contacted by FWW on August 18, 2006, about the unavailability of the four references listed in the bacteriophage final rule. FWW was informed that the review memos had been taken off the Agency's Web site to be purged of confidential information. While the 4 references cited in the bacteriophage final rule were unavailable to FWW for 13 days after the publication of the final rule, FWW did obtain them with more than half the 30-day period for objection still left.

With respect to the select portions of the petition that FWW objects to having received 21 days after the start of the 30-day objection period, we understand this objection to refer to the portions of the petition that FWW examined in

FDA's offices on September 8, 2006. These portions of the petition were not among the four references cited in the bacteriophage final rule and placed on public display as part of the petition docket. As is discussed previously, it would not be an efficient use of Agency resources to prepare the entire petition for release in advance of any requests to view the petition. However, FDA was nonetheless able to redact significant portions of the petition in an expedited manner and provide them for FWW's review on September 8, 2006.

FDA is denying the request for a hearing on this point because a hearing will not be granted unless there is a genuine and substantial factual issue to be resolved (§ 12.24(b)(1)), and resolution of the factual issue in the way sought is adequate to justify the action requested (§ 12.24(b)(4)). Furthermore, a hearing is justified only if the objections "draw in question in a material way the underpinnings of the regulation at issue" (*Pactra Industries v. Consumer Product Safety Commission*, 555 F.2d at 684), which is not the case with this objection.

V. Summary and Conclusions

Section 409 of the FD&C 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 a *Listeria*-specific bacteriophage preparation for treating RTE meat and poultry products, FDA concluded that the data presented by the petitioner to establish safety of the additive demonstrate that the use of the bacteriophage preparation is safe under the conditions of use stated in the regulation. The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. (*See, e.g., Silverman v. Foreman*, 631 F.2d 969, 972 (DC Cir. 1980).) 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. (*See* section 409(f)(1) of the FD&C Act.)

None of the objections received contained evidence to present a genuine and substantial issue of fact. Nor has the 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. In addition, FWW's request for a stay of the effectiveness of the August 18, 2006, regulation until a hearing is held is moot because FDA is denying the hearing request. FDA is confirming August 18, 2006, as the effective date of the regulation.

VI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. "Evaluating the Safety of Food Chemicals," National Research Council, National Academy of Sciences, Washington DC, p. 55.

2. Jacobs, T., A. Darji, N. Frahm, et al., "Listeriolysin O: Cholesterol Inhibits Cytolysis But Not Binding to Cellular Membranes," *Molecular Microbiology*, 28:1081-1089, 1998.

3. U.S. Department of Agriculture Nutritive Value of Foods, Home and Garden Bulletin Number 72, USDA, Agricultural Research Service.

4. Guyton, A.C., J.E. Hall, *Textbook of Medical Physiology* (9th ed.) Philadelphia: W.B. Saunders Co., p. 817, 1996.

Dated: March 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

[Docket No. FDA-2011-N-0003]

Tolerances for Residues of New Animal Drugs in Food; 2-Acetylamino-5-Nitrothiazole; Buquinolate; Chlorobutanol; Estradiol and Related Esters; Ethylenediamine; Florfenicol; Flunixin; Furazolidone; Hydrocortisone; Methylparaben; Methylprednisolone; Prednisolone; Prednisone; Progesterone; Propylparaben; and Salicylic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the revocation of tolerances for residues of

various substances in food because approval has been withdrawn for the underlying food additive petitions (FAPs) or new animal drug applications (NADAs). This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective March 23, 2011.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Section 512(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(i)) (21 CFR 514.105(a)) directs FDA to establish tolerances by regulation, as necessary, when a new animal drug is approved for use in food-producing animals. However, section 512(i) of the FD&C Act (21 CFR 514.115(e)) also obligates FDA to revoke such tolerance regulations upon the withdrawal of approval of the related NADA.

FDA has noticed that the animal drug regulations contain tolerances for residues of substances in food that were established by approval of FAPs for animal drug products prior to the Animal Drug Amendments of 1968 or by NADA for which an underlying application for use in a food-producing species is not currently approved. Following codification of the tolerance, the underlying FAP may have been withdrawn, or an NADA for the same drug product was not filed or was withdrawn, either voluntarily or for cause. When regulations for these products were removed or omitted from various redesignation rules, the appropriate conforming amendments to remove the revoked tolerances from part 556 (21 CFR part 556) were not made. The following chemical substances and new animal drugs have codified tolerances for which FDA finds no applications with corresponding approved conditions of use in food-producing animals:

1. *2-Acetylamino-5-nitrothiazole* (§ 556.20). In 1979, FDA acknowledged the voluntary withdrawal of approval of NADA 9-424 for use of 2-acetylamino-5-nitrothiazole for use in turkey feed and revoked 21 CFR 558.25 (44 FR 40888, July 13, 1979), but did not amend part 556 to remove the associated tolerances.

2. *Chlorobutanol* (§ 556.140). In 1963, FDA established a tolerance for chlorobutanol in milk of dairy animals at § 121.1131 (21 CFR 121.1131) incidental to the approval of an FAP for a combination drug, antibiotic/steroid intramammary infusion (28 FR 4948,

May 17, 1963). Section 121.1131 was redesignated as 21 CFR 135g.31 (35 FR 15372 at 15376, October 2, 1970) and as § 556.140 (40 FR 13802 at 13947, March 27, 1975).

3. *Estradiol and progesterone in edible tissues of lambs* (§§ 556.240 and 556.540). In 1973, FDA acknowledged the voluntary withdrawal of approval of a subcutaneous implant for use in lambs containing estradiol benzoate and progesterone under NADA 9-442 (38 FR 7481, March 22, 1973). Subsequently, FDA removed the approved conditions of use in 21 CFR 522.1940 (44 FR 6707 at 6708, February 2, 1979), but did not amend part 556 to remove the associated tolerances in uncooked edible tissues of lambs.

4. *Ethylenediamine* (§ 556.270). In 1965, FDA established a tolerance for ethylenediamine in milk of dairy animals at § 121.1184 (21 CFR 121.1184) incidental to the approval of an FAP for a combination drug, antibiotic intramammary infusion (30 FR 11952 at 11954, September 18, 1965). Section 121.1184 was redesignated as 21 CFR 135g.48 (35 FR 15372 at 15378) and as § 556.270 (40 FR 13802 at 13950).

5. *Furazolidone* (§ 556.290). In 1963, FDA established a tolerance for furazolidone in uncooked edible tissues of swine at § 121.2582 (21 CFR 121.2582) incidental to the approval of an FAP for use in medicated swine feed (28 FR 12664 at 12665, November 28, 1963). Section 121.2582 was redesignated as 21 CFR 121.1145 (30 FR 15845 at 15917, December 23, 1965), as 21 CFR 135g.36 (35 FR 15372 at 15376), and as § 556.290 (40 FR 13802 at 13950). In 1971, FDA proposed to withdraw approval of NADAs for use of furazolidone in food-producing animals on grounds that the drug, when administered to laboratory animals, was shown to produce tumors (36 FR 5927, March 31, 1971) and in 1991 withdrew approval after a full evidentiary hearing (56 FR 41902, August 23, 1991). Currently, there is no approved application for use of furazolidone in a food-producing species. A 1996 order codified a prohibition of extralabel use of furazolidone in food-producing animals (61 FR 57732 at 57743, November 7, 1996 as amended 67 FR 5470 at 5471, February 6, 2002). See 21 CFR 530.41(a)(7).

6. *Hydrocortisone* (§ 556.320). In 1970, FDA established a tolerance for hydrocortisone in milk of dairy animals at § 135g.3 (21 CFR 135g.3) incidental to the approval of an FAP for a combination drug, antibiotic/steroid intramammary infusion (35 FR 12332 at 12333, August 1, 1970). Section 135g.3