includes use of emergency equipment, including life rafts and associated equipment (such as pyrotechnic signaling devices), before the actual ditching occurs. Crewmembers are required to be trained in the proper use of emergency equipment. Moreover, when pyrotechnic signaling devices are required as part of a life raft's survival equipment, they are generally inaccessible without removing the raft itself. In cases where the life raft's survival kit is stored separately from the raft, locations are typically not readily available for passenger access until actually needed.

Part 135 Relief

An individual commenter, Net Jets, and the Regional Airline Association stated they are in favor of including relief for part 135 operations. An individual commenter stated that all of the justification for part 121 operations is true for part 135 operations, as well. Net Jets stated that similarly situated part 135 operators should be provided with the same relief as part 121 operators, and noted the similarities between part 121 dispatch/flight following systems and the flight locating requirements of part 135. Net Jets also stated that the Part 125/135 Aviation Rulemaking Committee (ARC) is addressing the issue as it applies to part 135 operations. Net Jets stated that a complete power loss of a part 25 certificated turbojet airplane is extremely low.

Although the requirements differ, the FAA agrees that similarities may exist between part 121 flight following requirements and part 135 flight locating requirements. Also, while some 135 operators conduct operations very similar to part 121 operators, many do not so it would not be appropriate to provide the same blanket relief to all 135 operators. However, if a particular part 135 operator's flight locating system meets all of the requirements of a part 121 flight following system, relief provided in this rule change may be sought by that operator and evaluated by the FAA through the exemption process.

The FAA agrees that complete engine failure of a part 25-certificated airplane is extremely low. However, engine failure is not the only precursor to a forced ditching. Onboard fires, flight control malfunctions, and fuel exhaustion have also resulted in ditching incidents.

The FAA looks forward to receiving recommendations from the Part 125/135 ARC when they are complete.

Pyrotechnic Signaling Devices Required as Part of a Life Raft

An individual commenter stated that the rule should contain a requirement for positive proof that a pyrotechnic device required as part of a life raft is, in fact, onboard and goes on to question how an operator would determine that the device is installed in the life raft.

It is incumbent upon an operator to demonstrate compliance with any applicable requirements for a particular operation. For example, an operator may maintain an inventory of life raft-related equipment to satisfy this requirement when the equipment must be carried onboard for over-water operations.

Conclusion

After consideration of the comments submitted in response to the final rule, the FAA has determined that no further rulemaking action is necessary. Amendment 91–285 remains in effect as adopted.

Issued in Washington, DC, on April 21, 2005.

Marion C. Blakey,

Administrator.

[FR Doc. 05–8453 Filed 4–26–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket Nos. 1998F–0052 and 1999F–0187 (formerly Docket Nos. 98F–0052 and 99F–0187)]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Neotame

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 authorizing the use of neotame as a nonnutritive sweetener in food. 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.

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 notices in the **Federal Register** on February 10, 1998 (63 FR 6762), and February 8, 1999 (64 FR 6100), announcing the filing of food additive petitions, FAP 8A4580 and FAP 9A4643, respectively, by Monsanto Co. to amend the food additive regulations in Part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of neotame as a nonnutritive sweetener for tabletop use (FAP 8A4580) and for general-purpose use in food (FAP 9A4643) where standards of identity do not preclude such use. The rights to these petitions were subsequently sold to the NutraSweet Co. In the **Federal Register** of July 9, 2002 (67 FR 45300), FDA issued a final rule permitting the safe use of neotame as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry. 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 August 8, 2002).

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 based 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.

Under 21 CFR 171.110 of the food additive regulations, 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 the

provision of the regulation or proposed order 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 neotame final rule, FDA received three submissions, within the 30-day objection period, objecting to the agency's safety evaluation of neotame as a general-purpose sweetener. Two of the submissions are essentially identical in content and assert that all of the studies that were discussed in the neotame final rule are meaningless because they are based on aspartame, which they claim has never been proven to be safe for use in food. Both of these submissions requested a hearing. The third submission questions the validity of the agency's exposure estimate for neotame and its metabolites. This same submission also asks a number of questions regarding the clinical studies that were conducted on human tolerance to neotame. The submission requested a hearing on both of these issues.

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 requestor; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; and (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).

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

FDA addresses each of the three 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.

Two submissions objected to the final rule asserting that all of the safety studies on neotame are meaningless because they are based on aspartame. Both submissions requested hearings on this point. As stated in the neotame final rule, to support the safety of neotame, the petitioner submitted, within the two petitions, a combined total of 113 preclinical, clinical, and special studies, plus an additional 32 exploratory and screening studies in a food master file on the safety of neotame and its metabolites, not aspartame. The objectors did not specifically address any of these studies. Further, the assertion that the safety evaluation of neotame is based on aspartame is baseless and completely false. 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)).

The third objection questioned the agency's exposure estimate for neotame and the clinical studies that were conducted and requested a hearing on these issues. However, the submission

provided no information that would support a reevaluation of the agency's exposure estimate or the clinical studies that were conducted. Therefore, this submission provides no basis for FDA to reconsider its decision to issue the final rule on neotame. Moreover, this submission provides no basis for granting a hearing because a hearing request must include specifically identified reliable evidence that can lead to resolution of a factual issue in dispute. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(2)). Therefore, FDA is denying the hearing requested by this submission.

V. Summary and Conclusions

Section 409 of the act requires that a food additive be shown to be safe prior to marketing. Under 21 CFR 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 neotame, FDA concluded that the data presented by the petitioner to establish safety of the additive demonstrate that neotame is safe for its intended use as a general-purpose sweetener and flavor enhancer in foods. The final rule did not authorize the use of neotame in meat and poultry.

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 F2d. 1307, 1314–1315 (DC Cir. 1979)).

None of the three 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: April 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8352 Filed 4–26–05; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R03–OAR–2005–VA–0001; FRL–7904–5]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; NO_X RACT Determinations for Four Individual Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the Commonwealth of Virginia's State Implementation Plan (SIP). The revisions were submitted by the Virginia Department of Environmental Quality (VADEQ) to establish and require reasonably available control technology (RACT) for four major sources of nitrogen oxides (NO_X). These sources are located in the Western Virginia Emissions Control Area. EPA is approving these revisions to establish RACT requirements in the SIP in accordance with the Clean Air Act (CAA).

DATES: This rule is effective on June 27, 2005, without further notice, unless EPA receives adverse written comment by May 27, 2005. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2005–VA–0001 by one of the following methods:

A. Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. Agency Web site: *http://www.docket.epa.gov/rmepub/*. RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: *campbell.david commat;epa.gov*.

D. Mail: R03–OAR–2005–VA–0001, David Campbell, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to RME ID No. R03–OAR–2005–VA–0001. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.docket.epa.gov/rmepub/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814–2182, or by e-mail at *quinto.rose@epa.gov*.

SUPPLEMENTARY INFORMATION: