FAA Response

The FAA appreciates the time and effort that persons expended to respond to this ANPRM. Although comments concerning overflights of the national parks, and specifically how those flights should be regulated, are somewhat polarized, many commenters gave the FAA specific advice that will be helpful in future rulemaking. Commenters have indicated, for example, that different parks have different needs, and that even within parks, some areas may have different priorities for restoring 'natural quiet'. We understand that while quiet technology aircraft can make a difference in noise levels, there must be some incentive for operators to obtain expensive equipment. Overall, both the FAA and NPS have gained a better understanding of the various positions on these issues, both from those representing air tour operators and those interested in preserving the beauty and quiet in our national parks.

Subsequent Rulemaking Efforts

On April 22, 1996, President Clinton issued a Memorandum to address the significant impacts on visitor experience in national parks. In this memorandum the President set out three goals: to place appropriate limits on sightseeing aircraft at the GCNP; to address the potential impact of noise at Rocky Mountain National Park; and, for the national park system as a whole, to establish a framework for managing aircraft operations over those park units identified in the NPS 1994 study as priorities for maintaining or restoring the natural quiet.

In response to this memorandum, the FAA and NPS established, under the authority of the Aviation Rulemaking Advisory Committee (ARAC) and the National Park Service Advisory Board, a National Parks Overflights Working Group (NPOWG). The NPOWG members were selected to represent balanced interests that included the air tour operators, general aviation users, other commercial interests, environmental and conservation organizations, and Native Americans. The NPOWG was given the task of reaching consensus on a recommended NPRM which would establish a process for reducing or preventing the adverse effects of commercial air tour operations over units of the National Park System.

The NPOWG met from May through November 1997. In December 1997, members presented a concept paper to both the ARAC and the NPS Advisory Board. Both advisory groups accepted the proposed concept, which provides a mechanism, a process, whereby each unit of the National Park System will determine the necessary restrictions for that unit based on a park management plan that will be developed by the FAA with guidance from the NPS and with input from all interested parties.

Following the acceptance of the concept by the ARAC and NPS Advisory Board, the FAA and NPS are assisting the NPOWG in developing an NPRM. The FAA anticipates that when the NPRM is ready for publication, it would also plan public meetings to gain additional comment on how the concept would work for individual parks.

Issued in Washington, DC on April 5, 1999.

David Traynham,

Assistant Administrator for Policy, Planning, and International Aviation.

Jacqueline Lowey,

Deputy Director, National Park Service.

[FR Doc. 99–8920 Filed 4–8–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98P–0968]

Food Labeling: Declaration of Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its ingredient labeling regulations to permit the use of ''and/or'' labeling for the various fish species used in the production of processed seafood products, i.e., surimi and surimi-containing foods. This action responds to a petition submitted by the National Fisheries Institute (NFI) requesting more flexible ingredient labeling for the fish ingredients used in the production of surimi products. This proposed rule would permit manufacturers of surimi and surimi-containing products to maintain a single label inventory identifying all of the fish species that may be used in the manufacture of the surimi product.

DATES: Comments by June 23, 1999. See section VIII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Felicia B. Satchell, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

''Surimi'' is a fish protein product made from minced fish meat that has been washed to remove fat, blood, pigments, odorous and other undesirable substances and that has been mixed with cryoprotectants such as sugar or sorbitol to prevent freezer burn (Ref. 1). The fish species used in surimi and surimi-containing products are primarily Alaskan pollock, Pacific whiting/hake, cod, and arrowtooth flounder. As an intermediate processed seafood product, surimi is then used in the formulation of a variety of finished seafood products, such as imitation crab and lobster meat.

Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)(2)) provides that the label of a food like surimi that is fabricated from two or more ingredients must bear the common or usual name of each ingredient. Section 403(i)(2) of the act further provides that when compliance with this requirement is impracticable, or results in deception or unfair competition, FDA can establish exemptions by regulation. FDA's regulations implementing section 403(i)(2) of the act generally require that ingredients used to fabricate a food must be declared on the label by their common or usual name in descending order of predominance by weight (§ 101.4(a)(1) and (b)(2) (21 CFR 101.4(a)(1) and (b)(2))). However, under section 403(i)(2) of the act, FDA has, through rulemaking, issued exceptions to the requirement in § 101.4(a)(1) and (b)(2) when the agency has concluded that compliance with these provisions is impracticable or may result in deception or unfair competition. For example, FDA allows ''and/or'' ingredient labeling when the agency believes it is impracticable for manufacturers to adhere to a fixed ingredient profile. The most recent rulemaking where FDA has provided for the use of ''and/or'' labeling is in the declaration of wax and resin coatings on fresh fruits and vegetables (58 FR 2850 at 2875, January 6, 1993).

With respect to the general requirements for compliance with section 403(i)(2) of the act, the agency has specifically outlined in guidance documents how ingredients in certain foods should be declared. For processed and/or blended seafood products that

are composed, all or in part, of surimi, FDA's Compliance Policy Guide (CPG) 540.700 advises that manufacturers of these products should declare the specific names of all seafoods used in the product in the ingredient statement in descending order of predominance. To comply with section 403(i)(2) of the act and § 101.4(a) and (b), ingredient statements on the labels of surimi and surimi-containing products that are made from more than one fish species must declare each of the fish species used to fabricate that food in descending order of predominance by weight (§ 101.4(a)).

II. The Petition

A. Requested Provisions

FDA received a citizen petition from the NFI (filed October 13, 1998, Docket No. 96P–0968) (hereinafter referred to as the petition) requesting that the agency revise CPG 540.700 to permit the use of ''and/or'' labeling in the ingredient declaration of the fish species used in surimi and surimi-containing foods (Ref. 2). Specifically, the petition requested that the CPG be revised as follows:

> The specific names of all seafoods used in the product shall appear in the ingredient statement in descending order of predominance (''pollock'' must be used as opposed to ''white fish''; ''snow crab'' rather than ''crab''), except that, if the manufacturer is unable to adhere to a constant pattern of fish species in the product, the listing of species need not be in descending order of predominance. Fish species not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may or may not be present, such as ''or,'' ''and/or,'' or ''contains one or more of the following:''.

The petition contends that the requested action would alleviate significant quality, manufacturing, logistical, and financial burdens that the surimi industry currently faces, yet still ensure that consumers receive truthful, nonmisleading information about the composition of surimi and surimi-containing products.

B. Basis for Requested Provisions

The request in the petition for permission to use ''and/or'' labeling for surimi-containing products was based on several arguments. While the agency finds merit in all of the arguments discussed in the petition, it will only discuss in this document those arguments that pertain to the standards set out in section 403(i)(2) of the act and form the primary basis on which the agency has been persuaded to propose an exception to the existing ingredient labeling regulations.

1. Due to Seasonality and Quota Limitations, Manufacturers are Unable To Adhere to a Constant Pattern of Fish Species in Producing Surimi and Surimi-Containing Foods

According to the petition, the commercial availability of a specific fish species used in the manufacture of surimi and surimi-containing foods is variable and depends upon several factors out of the manufacturer's control, including: The length of the harvesting season, the quota limitations for each species, and the cost. Each fish species is available for harvesting only during certain periods of the year. For example, the harvest season for pollock ''A'' normally opens in mid-January and runs through mid-February. The harvest season for Pollock ''B'' typically runs from mid-September through mid-October. Similarly, the harvest season for Pacific whiting begins in May and continues into the summer.

Harvest quotas will also impact on the availability of a particular fish species. According to the petition, only limited quantities of specific fish species may be harvested during a given season. Due to provisions established under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), harvest quotas are established through the National Fishery Management Program and are managed by regional fishery management councils. Once a quota has been filled, no more of that species may be harvested until the next season. (Thus, the actual length of a harvest season can be unpredictable, depending upon the type and number of companies or vessels entering a fishery, and the pace with which applicable quotas are filled.) Quotas fluctuate according to estimated species biomass, and, therefore, vary from season to season, and from year to year. In sum, the petition contends that, because surimi can be and is made from a variety of fish species, the variability in harvest seasons and quotas confounds prediction of the specific composition of surimi that will be available at any given time for processing into a finished seafood product.

2. FDA's Current Ingredient Labeling Requirements Place Unwarranted Burdens on Manufacturers of Surimi and Surimi-containing Foods by Forcing Them to Maintain and Coordinate Several Inventories of Species-specific Surimi and Contingent Labels That Declare the Specific Fish Species Used to Make the Surimi

The petition states that the associated label storage burdens (i.e., maintaining different label inventories for surimi-containing foods that account for all possible fish species or predominance combinations) are compounded because frozen surimi quickly loses its functionality during storage, and manufacturers are constantly forced to adjust overall product formulations to maintain consistent quality.[1] Therefore, the petition argues that modification of the existing ingredient labeling requirements would not only significantly reduce the economic burden on surimi manufacturers, but also promote the goal of effective management of harvestable resources.

The petition contends that because of the inventory constraints on holding multiple labels for the same product, administrative difficulties of ensuring that correct labels are used, and logistical problems of having multiple product codes for the same item, companies are effectively forced to produce finished surimi food products from single fish species. This becomes a problem, however, due to the limitations of availability of various fish species used to make surimi. Consequently, the petition contends that it is impracticable for manufacturers of surimi and surimi-containing foods to comply with the existing ingredient labeling regulations and that an exception in the form of ''and/or'' labeling is warranted. According to the petition, permitting the use of a single label that declares each of the fish species that may be present in the product would ease the impracticability and unwarranted burdens of the existing ingredient labeling requirements.

The petition also explains that, because the fish ingredients used in surimi are decharacterized through processing, the specific fish species used in surimi is unimportant and neither characterizes the food nor influences consumers' purchase decisions. According to the petition, finished surimi products have similar economic value and nutritional attributes regardless of the species originally used in its manufacture.

As noted previously, the fish species used in surimi and surimi-containing products are primarily Alaskan pollock, Pacific whiting/hake, cod, and

[1] The petition further mentioned that the limitations created by the existing ingredient labeling requirements also hinder the ability of the seafood industry to use conventional and innovative surimi processing technologies to optimize the yield of both target fish species (e.g., pollock, cod, Pacific whiting) and nontarget, by catch species (e.g., arrowtooth flounder) and that the North American Pacific Fishery Management Council has imposed increased utilization and recovery mandates on seafood harvesters and processors.

arrowtooth flounder. When making surimi, the fish are processed shortly after they are caught. They are headed, gutted, gilleted, skinned, deboned, and minced. Once minced, the meat is processed through a series of washes. After each wash, the minced fish is pressed through a rotary screen to dewater the product. The wash and screening steps are critical in removing blood, fat, pigments, and enzymes characteristic of the particular fish species used. Each wash step, beginning with the first, removes features associated with taste, smell, and color. The resultant fish ingredient is further refined, mixed with cryoprotectants, extruded into blocks, and frozen.

The petition argues that this processing produces a completely decharacterized myofibrillar (i.e., muscle fiber) protein such that even the most sophisticated laboratory techniques cannot determine with certainty the source fish of the protein. Likewise, the petition argues, this processing allows the interchangeability of different fish species because regardless of the fish species used, the resultant myofibrillar proteins are functionally interchangeable.

III. Agency Response

The agency has considered the arguments raised in the petition and finds that there is considerable merit in the need for more flexible ingredient labeling with regard to the particular fish species used in the production of surimi and surimi-containing foods. Information available to the agency (Ref. 1) supports the position stated in the petition that the processing of surimi sufficiently decharacterizes the fish protein such that the species from which the fish protein is derived is no longer distinguishable. In addition, the agency recognizes the limitations imposed by harvesting seasons and quotas on the availability of specific fish species, and the impracticability of maintaining different label inventories to reflect any and all possible formulation combinations. Consequently, the agency tentatively concludes that the existing ingredient labeling requirements are impracticable for the declaration of the fish ingredient in surimi and surimi-containing foods. Moreover, the agency is persuaded by the arguments presented in the petition that the use of a more flexible ingredient labeling requirement will not disadvantage consumers because the specific source of the fish protein has little bearing on the economic value, taste, or quality of the finished food. Under the provision the agency is proposing in this document, consumers who use the ingredient label to avoid certain foods for health-related reasons will still receive adequate information about the basic nature of the food and will be able to make informed purchase decisions. Thus, the agency tentatively finds that, like other permitted uses of ''and/or'' ingredient labeling, the use of such labeling for the declaration of the fish species in processed seafood products is consistent with other exceptions to the ingredient labeling requirements and would not compromise the type or amount of information received by the consumer regarding surimi and surimi-containing foods.

The agency notes, however, that the action requested in the petition, i.e., revision of CPG 540.700, is not an appropriate mechanism for the type of relief requested. As set out in section 403(i)(2) of the act, FDA can affirmatively sanction the use of ''and/or'' labeling only through notice and comment rulemaking. Thus, the agency is proposing to amend its ingredient labeling regulations in § 101.4(b) to provide for the use of ''and/or'' labeling of the specific fish species used in the fabrication of surimi and surimi-containing foods. (The agency notes that at the time a final rule is issued in this matter, a revised CPG also will be issued to reflect the final rule.)

IV. The Proposal

As noted in section III of this document, revising the CPG is not an appropriate mechanism to provide for the use of ''and/or'' labeling in the ingredient declaration of the fish protein species in surimi and surimi-containing foods. Consequently, the agency is not proposing the language that was suggested in the petition. However, the agency believes that the language that it is proposing in this document will effectively permit manufacturers of surimi and surimi-containing foods to maintain a single label inventory for use on such products formulated from protein derived from a variety of fish species. Furthermore, the agency believes that the action it is proposing in this document is consistent with its other provisions providing flexibility in ingredient declaration of certain ingredients. Specifically, the agency is proposing that the specific fish species may be declared using ''and/or'' labeling to list the fish species that are sometimes used in the food. Considering the information presented in the petition regarding the processing of the fish ingredient coupled with other information available to the agency describing the production of surimi (Ref. 1), the agency believes that a term such as ''fish protein'' could be used to describe the fish ingredient used in the production of surimi. For example, a manufacturer of a processed seafood product that contains surimi could list the various fish species that might be used to produce the surimi in the product's list of ingredients by stating ''fish protein (contains one or more of the following: Pollock, cod and/or pacific whiting).''

V. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of this proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. FDA finds that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this proposed rule is not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

FDA agrees with the petitioner that the current combination of seasonal species harvests, harvesting limits, labeling regulations, and limited product storage times places an unwarranted and costly logistical burden on surimi manufacturers. This combination of circumstances forces surimi manufacturers to maintain and coordinate several inventories of species-specific surimi and contingent labels that declare the specific fish species used to make the surimi. The convergence of these conditions also hampers the seafood industry's efforts to use conventional and innovative surimi processing technologies to optimize fishery yield.

This proposed rule will mitigate the logistical burden faced by surimi manufacturers. Because surimi manufacturers will be able to maintain a single label inventory and use innovative technologies, they will be able to operate more efficiently. Because of lower production costs, consumers may see slightly lower prices for surimi. Because of the greater flexibility for species usage, the goals of fisheries management will be easier to achieve.

This proposed rule will not result in any increase in societal costs. Because the proposed rule is permissive, there are no costs imposed on producers. Because the new labels adequately inform consumers, there will be no costs to them in terms of lost information or increased search costs.

B. Small Entity Analysis

FDA has examined the impacts of this proposed rule under the Regulatory Flexibility Act (RFA). The RFA (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small businesses and other small entities. In compliance with the RFA, FDA finds that this proposed rule will not have a significant impact on a substantial number of small entities.

Because this proposed rule imposes no costs, it will not have a significant impact on a substantial number of small entities. Accordingly, under the RFA (5 U.S.C. 601–612), the agency certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of this proposed rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This rule does not trigger the requirement for a written statement under section 202(a) of the UMRA because it does not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by State, local, and tribal governments in the aggregate, or by the private sector, in any one year.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains ingredient declaration provisions that fall within the scope of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The agency tentatively concludes that the proposed provisions set forth below for the declaration of fish ingredients using ''and/or'' labeling would not impose any new information collection requirements because they create an exception from existing ingredient declaration requirements to make compliance easier. The ingredient declaration burden under § 101.4(b) has been approved by the Office of Management and Budget (OMB control number 0910–0381). To ensure that no additional burden has been overlooked, however, FDA seeks public comment on this tentative conclusion.

VIII. Comments and Proposed Dates

Interested persons may, on or before June 23, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above, between 9 a.m. and 4 p.m., Monday through Friday.

FDA proposes that any final rule that may issue based on this proposal become effective on the date that it is published in the **Federal Register**.

IX. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Lee, C. M., ''Surimi Process Technology,'' *Food Technology*, pp. 69–80, 1984.

2. Letter from Roy E. Martin to the Food and Drug Administration, dated October 13, 1998.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.4 is amended by adding paragraph (b)(23) to read as follows:

§ 101.4 Food; designation of ingredients.

* * * * *

(b) * * *

(23) When processed seafood products contain fish protein ingredients consisting primarily of the myofibrillar protein fraction from one or more fish species and the manufacturer is unable to adhere to a constant pattern of fish species in the fish protein ingredient, because of seasonal or other limitations of species availability, the common or usual name of each individual fish species need not be listed in descending order of predominance. Fish species not present in the fish protein ingredient may be listed if they are sometimes used in the product. Such ingredients must be identified by words indicating that they may not be present, such as ''or'', ''and/or'', or ''contains one or more of the following:'', e.g., ''fish protein (contains one or more of the following: Pollock, cod, and/or pacific whiting)''.

Dated: March 27, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8795 Filed 4–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–182N]

Schedules of Controlled Substances: Proposed Placement of Ketamine Into Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of withdrawal of proposed rule.

SUMMARY: The Drug Enforcement Administration (DEA) is withdrawing a Notice of Proposed Rulemaking (NPRM) which was published on June 2, 1981 (46 FR 29484). This NPRM proposed the placement of the substance ketamine, and salts thereof, into Schedule III of the Controlled Substances Act (CSA). In 1981, however, the DEA concluded that evidence of actual abuse was not sufficient to proceed with the rulemaking process. The DEA did not withdraw the NPRM, but continued to monitor the diversion and abuse of the drug. In light of additional evidence, the DEA now has sufficient data to proceed with the control of ketamine.