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]

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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.

So as to eliminate any confusion which may arise regarding the basis of the proposed action, the DEA is withdrawing the original NPRM (46 FR 29484) and under a separate notice in this issue of the **Federal Register**, the DEA is publishing a new NPRM which proposes the placement of the substance ketamine, its salts, isomers, and salts of isomers, into Schedule III of the CSA.

DATES: The proposed rule is withdrawn on April 9, 1999.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: 202–307–7183; FAX: 202–307–8570.

SUPPLEMENTARY INFORMATION: On June 2, 1981, the DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (46 FR 29484). The NPRM proposed to add the noncontrolled substance ketamine and any salts thereof to Schedule III of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). The DEA received seven letters in response to the NPRM. Comments in support of the proposed action were received from the American Veterinary Medical Association and a professor at the Texas A & M University, College of Veterinary Medicine. Comments in opposition were received from the Warner-Lambert Company, the Humane Society of the United States, the Division of Comparative Medicine at the Johns Hopkins University School of Medicine, the Department of Laboratory Animal Medicine at the Southwest Foundation for Research and Education, and the Director of Scientific Support Services, Primate Research Institute at the New Mexico State University. No requests for a hearing were received.

The DEA, after careful consideration, determined to postpone proceeding with the proposed regulatory action. While the substance's potential for abuse was established, the DEA concluded that the number of documented cases of abuse of the substance was insufficient to justify the regulatory action in 1981. The DEA did not withdraw the NPRM and terminate further rulemaking on the proposal, but continued to monitor the diversion and abuse of ketamine. In 1992, an increase in the number of cases of diversion and abuse was first noted. Elsewhere in this issue of the **Federal Register**, the DEA publishes a new NPRM, which results from the current experience as it relates to the diversion and abuse of ketamine. So as to eliminate any confusion which might arise regarding the basis of the proposed action, the DEA is withdrawing the 1981 NPRM (46 FR 29484 June 2, 1981) and terminating further rulemaking on this proposal.

Dated: April 2, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99–8812 Filed 4–8–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–183P]

21 CFR Part 1308

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

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA). It proposes the placement of the substance ketamine, including its salts, isomers, and salts of isomers, into Schedule III of the Controlled Substances Act (CSA). This proposed action is based on an evaluation of the relevant data by the DEA and a recommendation from the Assistant Secretary for Health and Surgeon General of the Department of Health and Human Services (DHHS) that ketamine and products containing it be placed into Schedule III of the CSA. The effect of this proposed action will be to discourage the diversion and abuse of ketamine, and subject ketamine to the regulatory, civil and criminal controls of a Schedule III controlled substance.

DATES: Comments and objections must be received on or before June 8, 1999.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537; Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: 202–307–7183; FAX: 202–307–8570.

SUPPLEMENTARY INFORMATION: Ketamine hydrochloride has been marketed in the United States since 1971 as a rapid-acting general anesthetic. It is used in both human and veterinary practice. Chemically, ketamine is related to PCP, a Schedule II controlled substance. The effects produced with use of ketamine are similar, although less intense and shorter in duration, to those produced by PCP.

The DHHS, by letter of March 18, 1981, recommended to the DEA that ketamine and products containing it be place into Schedule III of the CSA. The DEA published a notice of proposed rulemaking (NPRM) (46 FR 29484, June 2, 1981) which proposed the placement of the substance ketamine and salts thereof, into Schedule III of the CSA. In response to the NPRM, the DEA received seven letters. Comments in support of the proposed action were received from the American Veterinary Medical Association and a professor at the Texas A & M University, College of Veterinary Medicine. Comments in opposition were received from the Warner-Lambert Company, the Humane Society of the United States, the Division of Comparative Medicine at the Johns Hopkins University School of Medicine, the Department of Laboratory Animal Medicine at the Southwest Foundation for Research and Education, and the Director of Scientific Support Services, Primate Research Institute at the New Mexico State University. On review of the comments and the yearly average of four documented instances of diversion or abuse between 1975 and 1981, the DEA determined that the incidence of actual abuse was not sufficient to sustain the scheduling action. The DEA continued to monitor the situation.

The DEA summarized the relatively little actual abuse information available to it, and by letter of August 14, 1984, asked the DHHS if its previous recommendation for control of ketamine as a Schedule III controlled substance should stand. The DHHS, by letter of November 29, 1984, requested the information of abuse to which the DEA had referred. The DEA furnished the information to the DHHS by letter of February 18, 1985. By letter of September 8, 1986, the DHHS reaffirmed the recommendation to place ketamine into Schedule III of the CSA. On this occasion, as earlier, the DEA determined that the incidence of actual abuse, roughly five documented cases of diversion or abuse per year for the 1980–1986 period, was not sufficient to sustain the scheduling action and continued to monitor the situation.

Since 1992, 775 reports of ketamine diversion or abuse have been received by the DEA. The incidence of law enforcement encounters of individuals selling the drug, under its influence, or who had it in their possession, along with the wide geographic distribution of the encounters, the involvement of teenagers and young adults, the occurrence of veterinary clinic