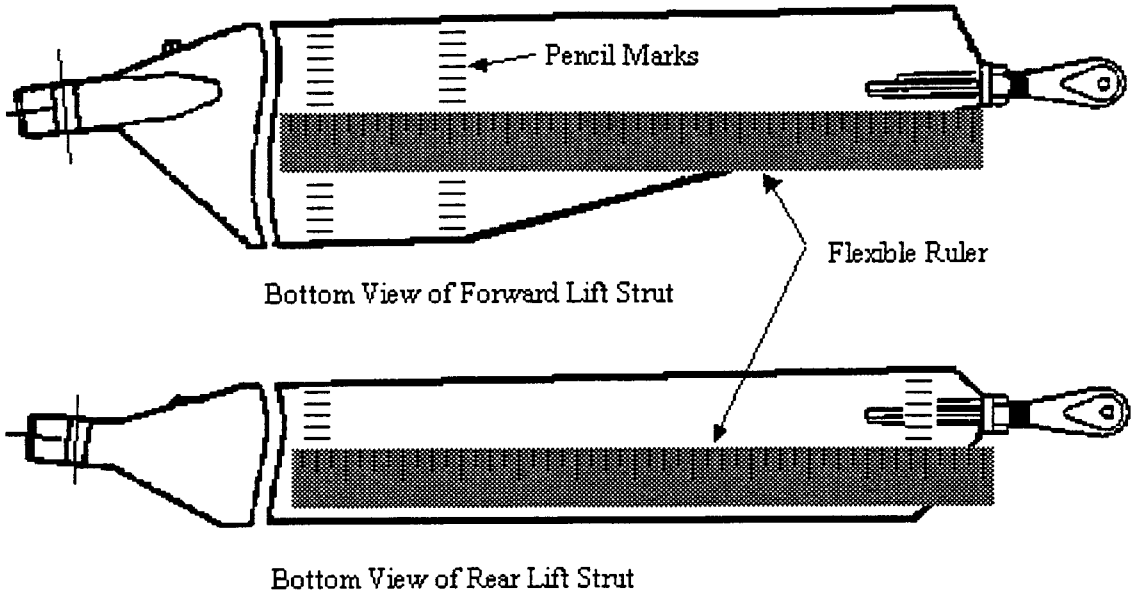

Figure 1

Issued in Kansas City, Missouri, on April 16, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 102

[Docket No. 94P–0043]

Crabmeat; Amendment of Common or Usual Name Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulation for crabmeat by adding the species *Callinectes sapidus* (*C. sapidus*) to those listed in the regulation and to provide that the common or usual name of crabmeat derived from this species is ''Blue crabmeat.'' FDA is further proposing, on its own initiative, to adopt common or usual names for 18 additional crab species. FDA is proposing these names based on ''The Seafood List'' and the information provided in the National Blue Crab Industry Association (NBCIA) petition. This proposal, which is in response to a citizen petition submitted by the NBCIA, is intended to allow crabmeat packers to properly identify their product so that consumers can make informed decisions.

DATES: Written comments by July 7, 1998. See section IV of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Center for Food Safety and Applied Nutrition (HFS–416), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3160.

SUPPLEMENTARY INFORMATION:

I. Background

A. Crabmeat Labeling

The NBCIA, 1525 Wilson Blvd., suite 500, Arlington, VA 22209, filed a petition on February 15, 1994, to amend the common or usual name regulation for crabmeat (§ 102.50 (21 CFR 102.50)) to provide that the common or usual name of crabmeat derived from the species *C. sapidus* is ''Blue crabmeat.''

Section 102.50 lists the following genera and species of crabs and the associated common or usual name of the meat from these crabs: *Chionoecetes opilio*, *Chionoecetes tanneri*, *Chionoecetes bairdii*, and *Chionoecetes angulatus* as Snow crabmeat; *Erimacrus isenbeckii* as Korean variety crabmeat or Kegani crabmeat; *Lithodes aequispina* as Brown King crabmeat; *Paralithodes brevipes* as King crabmeat or Hanasaki crabmeat; and *Paralithodes camtschaticus* and *Paralithodes platypus* as King crabmeat. (Note: The latter listing is currently incorrect in the Code of Federal Regulations (CFR). The CFR lists the common or usual names of *Paralithodes camtschaticus* as King crabmeat and *Paralithodes Platypus*. This error is being corrected in this document.)

FDA has been dealing with common or usual name issues involving crabmeat since 1954. In the **Federal Register** of April 8, 1954 (19 FR 2013), FDA announced its policy for the appropriate labeling of imported canned crabmeat. FDA later codified this policy and the other common or usual names for crabmeat in § 102.50 when it issued part 102—Common or Usual Names For Nonstandardized Foods (21 CFR part 102) in 1973 (38 FR 6966, March 14, 1973).

Guidance on the appropriate labeling of the crabmeats derived from species that are not listed in § 102.50 is set forth in the agency's Compliance Policy Guides (CPG 7108.04). Under this guidance, products derived from domestic sources that are labeled as ''crabmeat,'' without additional qualification, are generally accepted as being derived from *C. sapidus* (blue crab), historically one of the most common and widely recognized sources of crabmeat in the United States. In labeling other species of crab, the CPG encourages the use of a prefix that

identifies the country where the crab was caught (e.g., ''Taiwan Crabmeat'').

The NBCIA petition asserted that this policy no longer ensures that the meat of *C. sapidus* is unambiguously identified. The petition argued that consumers in the United States are being misled because, while they have come to expect that products that are labeled only as ''crabmeat'' are derived from *C. sapidus*, in many instances, other, less desirable crabmeats are being substituted, in whole or in part, for the expected *C. sapidus* meat. Therefore, the petitioner requested that FDA establish by regulation that the common or usual name ''Blue crabmeat'' applies only to the meat of *C. sapidus*, thereby ensuring that consumers will not be misled about the source and nature of the crabmeat.

B. Common or Usual Name Provisions

The common or usual name of a food is the prevalent and meaningful name by which consumers ordinarily identify the food. This vernacular name may lack the specificity of the scientific or technical name of a food, but an appropriate common or usual name permits the public to distinguish between similar foods that are available in the marketplace. The common or usual name of a food may be established by a history of common usage or by regulation. Section 102.5 requires that the common or usual name of a food accurately identify, in simple and direct terms, the basic nature of the food and its characterizing properties. The name must be uniform among all identical or similar products. In fact, under 21 CFR 101.3(b)(1), a food with a common or usual name that has been established by regulation is misbranded if it is not identified by that name (see also section 403(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(b)).

Before proposing a common or usual name regulation, FDA tries to ensure that the name that it is considering is not false or misleading within the meaning of section 403(a) of the act, and that the name conforms to the provisions of § 102.5. Moreover, to prevent confusion and deceptive economic practices, the agency must ensure that the name is not inappropriately similar to one that has already been established by regulation.

In the case of crabmeats, to conform to these principles, the common or usual name needs to clearly identify the characterizing properties that consumers in the United States associate with the meat of a particular species or group of crab species (e.g., see 59 FR 36103, July 15, 1994). In some cases a geographical prefix serves this purpose by alerting the consumer that the meat is not that of domestic species.

C. Need to Establish a Common or Usual Name by Regulation

Section 403(a)(1) of the act states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Under section 403(b), a food is misbranded if it is offered for sale under the name of another food. If a less valuable crabmeat is substituted for the species represented on the label or labeling, the product is adulterated under section 402(b)(2) of the act (21 U.S.C. 342(b)(2)), which states that a food shall be deemed to be adulterated if any substance has been substituted wholly or in part thereof (i.e., economic adulteration). Consequently, it is a clear violation of the act when a food such as crabmeat is not correctly identified on its label or in its labeling.

The agency may provide guidelines about how to label a class of foods, as in the case of fish and crabmeat, so that they are identified in a manner that promotes honesty and fair dealing in the interest of consumers. Nonetheless, false or misleading labeling practices sometimes arise that persuade FDA of the need to require the use of a common or usual name that will ensure that consumers are able to make fair value judgments about a food they buy. For example, a regulation prescribing a common or usual name may become necessary when there is not consistent adherence to a guideline on labeling practice (e.g., to the recommendation in CPG 7108.04 to provide the name of the country of origin as a prefix to ''crabmeat'' for crabmeat other than that of *C. sapidus*), when guidelines are not available, or when the guidance provided would not adequately resolve differences that distinguish similar foods, (e.g., the King crabmeats listed in § 102.50 that are harvested from the same waters).

Such a situation has arisen with respect to *C. sapidus*. As explained in section II of this document, FDA has become convinced that its admonition to marketers to follow the guidance in CPG 7108.04 is not being followed. As a result, many consumers are not being appropriately informed of the identity of the crabmeat that they are buying. Therefore, under § 102.19, FDA is proposing to adopt ''Blue crabmeat'' as the common or usual name of meat from the species *C. sapidus* and to adopt common or usual names for crabmeat derived from 18 other species of crab of which the agency is aware.

II. Grounds for the Petition

The NBCIA petition requested that FDA amend § 102.50 to include the species *C. sapidus* and to provide for the use of ''Blue crabmeat'' as the common or usual name of the meat of this species.

The petition contended that it is necessary for FDA to establish a common or usual name regulation for the following reasons:

(1) Even though *C. sapidus* is commonly known as ''blue crab,'' there has also been wide acceptance of the generic term ''crabmeat'' to refer to its meat because it is by far the most commonly available type of crabmeat in many areas of the United States. It has become commonplace, however, to import and repack, in the United States, crabmeats that are generally of lower value, primarily derived from non-*C. sapidus* species, and to label them also as ''crabmeat.''

(2) In some cases the imported crabmeat is blended with higher value domestic blue crabmeat and misrepresented as being entirely *C. sapidus*.

(3) Industry observations and Federal and State enforcement activities provide evidence that the country of origin of imported crabmeat often does not appear on the label after the meat has been repacked in the United States, even though U.S. Customs Service regulations require that the labels of imported products identify the country of origin unless it has been substantially transformed.

(4) In the absence of a regulation, there are no binding rules to determine which crabmeat products may be appropriately identified by the name ''blue crabmeat.''

In support of its contention that the imported meats of other crab species are being substituted for and represented as domestic *C. sapidus*, the petition included a copy of a newspaper account of a processor convicted in the State of Virginia of misbranding imported crabmeat by representing it as locally harvested domestic crabmeat (i.e., *C. sapidus*). The petition also included a copy of an Import Alert issued by FDA for the detention of misbranded seafoods, including products identified as blue crabmeat (No. 16–04—Revised, December 6, 1988). The Import Alert advised FDA inspectors to conduct surveillance sampling and to review the import documents of incoming seafoods to prevent the unlawful entry of ''various species of fish or other seafood offered for entry into the United States under the name of a fictitious, incorrect, or substituted species.'' The alert further

advised that inspectors should sample entries of seafood labeled as a species not common to the exporting country. The alert included as guidance an appendix listing seafoods associated with previous misbranding events, and the market names of species that might be substituted, their scientific or likely fictitious name, and the region or country from which specific species are normally available.

The petition asserted that ''blue crab'' is the appropriate common or usual name to codify for *C. sapidus* because it is the widely accepted common or usual name for this species. FDA acknowledges that it has been the agency's longstanding policy to accept ''blue crab'' as the common or usual name for *C. sapidus*. The Import Alert, as well as the CPG for the appropriate labeling of crabmeats, demonstrate not only FDA's acceptance of the common or usual name ''blue crabmeat,'' but also attest to the measures the agency has taken to deal with the ongoing problem associated with the proper identification and labeling of crabmeats. For example, CPG 7188.04 states that ''Product labeled as 'crabmeat,' from domestic sources, without qualification are generally accepted to have been derived from the blue crab, *Callinectes sapidus*.'' Similarly, the petition noted that in the appendix of Import Alert No. 16–04—Revised, FDA identified ''blue crabmeat'' as the market name for *C. sapidus* and identified its source as the Atlantic Ocean. Whenever possible, FDA recommends the use of the established common or usual name of a food as the market name.

More recently, FDA identified *C. sapidus* with the common name ''blue crab'' in ''The Seafood List,'' which is the agency's guide to acceptable market names and common names for the species of food fish and invertebrates sold in U.S. interstate commerce that do not have common or usual names established by regulation (57 FR 47144, September 14, 1994). In compiling this guide, FDA started with its own information and experience, but the agency relied primarily on consultation with seafood experts and authoritative works on seafood nomenclature.

FDA has confirmed that authoritative nomenclature and trade publications continue to accept ''blue crab'' as the common or usual name for *C. sapidus*. For example, the American Fisheries Society Special Publication 17, ''Common and Scientific Names of Aquatic Invertebrates from the United States and Canada: Decapod Crustaceans,'' addresses adherence to uniform scientific and common nomenclature of aquatic invertebrates and recognizes only *C. sapidus* by the common name ''blue crab'' (Ref. 1).

A nomenclature reference with an international perspective, ''Fish: Five-Language Dictionary of Fish, Crustaceans and Molluscs,'' also lists *C. sapidus* as ''blue crab'' (Ref. 2). Similarly, the ''Multilingual Dictionary of Fish and Fish Products,'' identifies ''blue crab (Atlantic-U.S.A.)'' as *C. sapidus* (Ref. 3).

Consequently, FDA agrees with the petitioner that ''blue crab'' is the common or usual name for *C. sapidus*. That name is not only descriptive of the remarkably distinctive blue coloration of the animal's claws, but it is the meaningful and informative name that has been established by common use.

III. The Proposed Regulation

The U.S. Government, including FDA, is concerned about recurring incidents of misrepresentations about the content of domestic products that are derived in whole or in part from imported crabmeat. The U.S. Customs Service expressed this concern in a detailed examination and ruling that addressed the relationship between the extent of domestic processing performed on imported crabmeat (i.e., whether a ''substantial transformation'' has occurred) and the requirement for country of origin labeling on the finished consumer product (Ref. 4). The U.S. Customs Service ruling held that:

> * * * the domestic processing of imported crab meat by thawing, sorting, blending with domestic crabmeat, canning and pasteurization does not constitute a substantial transformation. Accordingly, the repacked crab meat is subject to the country of origin marking requirements of 19 U.S.C. 1304 and 19 CFR 134 * * *.

The ruling also concluded that none of the above processing operations ''taken individually or together is sufficient to substantially transform the crab meat into a product with a different name, character or use.'' (Ref. 4)

The U.S. Customs Service ruling underscores the petitioner's contention that the labeling of imported crabmeats is misleading, particularly with regard to providing consumers with information that will enable them to distinguish these crabmeats from domestic *C. sapidus* similarly labeled as ''crabmeat.'' In light of the record of misbranding of imported crabmeat products, including the agency's own efforts to detect and prevent such abuses, FDA tentatively concludes that the petitioner's claims that consumers are being misled are valid.

The agency agrees with the petitioner that, in the absence of a regulation that requires *C. sapidus* to be labeled as ''Blue crabmeat,'' there is nothing that would require a conclusion that another crabmeat is misbranded when it is identified as ''Blue crabmeat.'' FDA also agrees with the petitioner that the generic ''crabmeat'' labeling of imports misleads because it implies that the crabmeat is domestic Blue crabmeat. Moreover, the term ''crabmeat'' does not adequately identify the food or allow consumers to distinguish between similar crabmeats that differ in value.

This proposal will remedy this situation because, if the agency adopts the proposed regulation, the meat of *C. sapidus* is misbranded unless it is labeled ''Blue crabmeat,'' and, conversely, if crabmeats of other species are labeled as ''Blue crabmeat,'' they also will be misbranded. Thus, the proposed action will protect consumers from the confusing and misleading labeling of *C. sapidus* meat and from non-*C. sapidus* meat being labeled as ''Blue Crabmeat.''

Consequently, FDA tentatively finds that the adoption of the common or usual name ''Blue crabmeat'' for *C. sapidus* meat will promote honesty and fair dealing in the interest of the consumer, and that this name accurately identifies, in simple and direct terms, the basic nature of the food and its characterizing properties. Accordingly, the agency tentatively concludes that § 102.50 should be amended to include the name ''Blue crabmeat'' as the common or usual name for the meat of *C. sapidus*.

However, FDA is not persuaded that this amendment will fully respond to the labeling concerns raised and reflected in the petition. Even if this proposed action becomes final, the meat of other crab species not listed in § 102.50 would continue to be labeled simply as ''crabmeat,'' which many consumers will interpret as meaning that the meat is from *C. sapidus*. For this reason and because of the persistent misrepresentation of crabmeats, FDA has tentatively concluded that the amendment requested by the petitioner is necessary but not sufficient to prevent the continuing abusive crabmeat labeling practices reviewed here. Therefore, the agency is proposing, on its own initiative, to amend § 102.50 more broadly than requested and to provide that all crabmeats must be identified on their label or labeling by the common or usual name of the species from which they are derived, as identified by FDA in ''The Seafood List.''

The extension of § 102.50 to include the common or usual name of all crabmeats is consistent with § 102.5(a): ''Each class or subclass of food shall be given its own common or usual name

that states, in clear terms, what it is in a way that distinguishes it from different foods.'' Under this proposal, consumers will have a means of differentiating among these similar foods. Products labeled simply as ''crabmeat'' will be misbranded.

Moreover, FDA tentatively concludes that it is appropriate and consistent with the efficient use of agency resources, to include these additional common or usual names in one amendment to § 102.50, rather than to continue to propose separate rulemakings to codify these names on a piecemeal basis, as it has since 1954.

As discussed under section II of this document, FDA has already expended considerable public resources to make ''The Seafood List'' available. It is an authoritative compendium of seafood nomenclature issued by FDA to promote the consistent and informative labeling of seafood species. To aid in their proper identification, this publication provides the scientific, ''common,'' and recommended market names (and in some cases regional vernacular names as well) for all of the domestic and imported species of finfish and invertebrates (shrimp, shellfish, and crustaceans) that are sold interstate in significant amounts as food in the United States.

The names entered under the ''Market'' heading in ''The Seafood List'' are the common or usual names of the species that have been established by common usage or by regulation. It is not uncommon to find that closely related species have the same common or usual (market) name. This also is the case with the species listed in § 102.50, where the meat from three different species of the *Paralithodes* genera share the common or usual name ''King crabmeat.'' The names under the heading ''Common'' in ''The Seafood List'' are the English language equivalent of the scientific name, and not the common or usual name, although these two types of common name frequently are very similar. When a common or usual name has not been established for a species, FDA recommends the use of the listed ''common'' name as an appropriate market name.

In addition to the common or usual names of the 6 crabmeats (from 9 species) that are currently listed in § 102.50, ''The Seafood List'' identifies the following 19 crab species by their scientific and common or usual (market) names: *Callinectes sapidus* (Blue crab), *Lithodes antarcticus* (Centolla crab), *Lithodes murrayi* (Centolla crab), *Paralomis granulosa* (Deepsea crab), *Cancer magister* (Dungeness crab), *Geryon fenneri* (Golden crab), *Cancer borealis* (Jonah crab), *Neolithodes brodiei* (Lithodes crab), *Geryon quinquedens* (Red crab), *Cancer irroratus* (Rock crab), *Cancer pagurus* (Rock crab), *Jacquinotia edwardsii* (Spider crab), *Maja squinado* (Spider crab), *Menippi adina* (Stone crab), *Menippi mercenaria* (Stone crab), *Callinectes arcuatus* (Swimming crab), *Callinectes toxotes* (Swimming crab), *Portunus pelagicus* (Swimming crab), and *Portunus puber* (Swimming crab).

FDA tentatively finds that, given the process that has gone into identifying and verifying the scientific and common or usual names of the crab species included in ''The Seafood List,'' it is appropriate to codify them in § 102.50 *Crabmeat*. Accordingly, FDA proposes to add the scientific and corresponding common or usual names of the 19 crab species listed in ''The Seafood List'' to § 102.50.

FDA solicits public comment on whether the agency should require, as it has proposed, that all crabmeat labeling include the use of an appropriate common or usual name to provide consumers with a more complete identification of the crabmeats available in the marketplace. FDA also solicits comment on whether there are other crab species that should be included in § 102.50, and, if there are, what the common or usual names is of each of these species.

If this proposal is finalized, anyone engaged in the interstate commerce of a crabmeat that is not listed in § 102.50 will have to petition FDA to include that species in the common or usual name regulation. The petition should demonstrate either the existence of an accepted common or usual name or propose to establish an appropriate one.

In recent years, FDA has developed a computer data base known as the ''Regulatory Fish Encyclopedia'' (RFE) to help ensure that the economic adulteration of seafoods can be detected and confirmed by scientific methods. As an aid to the identification of species by FDA field investigators, industry, and the public, the RFE is readily accessible on the Internet (vm.cfsan.fda.gov/~frf/rfe0.html) and from FDA's World Wide Web site. The RFE makes available high resolution, annotated color images of more than 60 authenticated fish species, as well as the unique electrophoretic patterns of the flesh proteins of about two-thirds of these species (i.e., their ''biochemical fingerprints'') (Ref. 5). Thus, in addition to a visual comparison of their anatomical features, an authentic protein pattern of a species that is displayed in the RFE can be compared with one obtained by isoelectric focusing methods from a suspected substitute species to determine whether misbranding and economic adulteration have occurred.

FDA is in the early stages of collecting and photographing authenticated species of various crabs, including *C. sapidus*; and the agency has plans to determine the unique biochemical pattern of their flesh proteins or, if necessary because crabmeat is often cooked, to determine the patterns of their cellular DNA (deoxyribonucleic acid) components for inclusion in the RFE. Thus, the RFE resources, when combined with requirements for the unambiguous labeling of these foods as proposed herein, will provide FDA with an effective means of establishing the identity of different crabmeats and combating economic fraud.

Under the proposed action, crabmeats that are labeled as ''Blue crabmeat'' and found to consist in whole or in part of crabmeat from other than *C. sapidus* will be misbranded and may be adulterated and will be subject to compliance action by the agency. Similarly, all other crabmeat will be misbranded unless labeled in accordance with the common or usual (market) name given in § 102.50.

Therefore, after a careful review of the petition and consideration of all of the available information, FDA is proposing to amend § 102.50 *Crabmeat*, by adding the crabmeat of the species *C. sapidus*, identified by the common or usual name ''Blue crabmeat.'' FDA is also proposing to amend § 102.50 by adding the scientific names of 18 additional crab species and the associated 11 common or usual names of their crabmeats as identified in ''The Seafood List.'' For the ease of the reader, FDA is proposing to further revise the table in § 102.50 by placing the ''Common or usual name of crabmeat'' in the first column followed by the ''Scientific name of crab'' in the second column. FDA also is correcting an inadvertent error that occurred in the **Federal Register** of July 3, 1995 (60 FR 34459 at 34460), in the scientific name column whereby the scientific name *Paralithodes Platypus* was incorrectly placed in the ''Common or usual name of crabmeat'' column and the word *Platypus* was incorrectly capitalized.

The impacts of this proposed rule on U.S. consumers and businesses are discussed in section V of this document. However, this proposed rule may also raise international trade issues that are not discussed in section V of this document. International trade issues may arise because the labeling changes necessitated by common or usual names may increase the demand for certain species of crab and decrease the demand

for other species of crab and because different countries and regions may harvest different species of crab. In some cases, these changes in demand will simply reflect preexisting differences in the value consumers place on the different species of crab. However, in other cases, these changes in demand might result from adverse consumer attitudes towards certain of the proposed common or usual names. For example, some consumers might find the name ''Spider crabmeat'' unappealing, creating an aversion to Spider crabmeat that did not previously exist. International trade effects caused by adverse consumer attitudes toward certain of the proposed common or usual names would ordinarily be considered a greater cause of concern than international trade effects caused by preexisting consumer preferences for different species of crab. FDA requests information on the international trade effects of this rule.

IV. Effective Date

The agency periodically has established by final rule in the **Federal Register** uniform effective dates for compliance with food labeling requirements (see, e.g., the **Federal Register** of December 27, 1996 (61 FR 68145)). FDA proposes that any final rule that may issue based upon this proposal become effective in accordance with a uniform effective date for compliance with food labeling requirements, which is established by final rule in the **Federal Register** and which is not sooner than 1 year following publication of any final rule based upon this proposal. The final rule would apply to affected products initially introduced or initially delivered for introduction into interstate commerce on or after its effective date. However, FDA notes that it generally encourages industry to comply with new labeling regulations as quickly as feasible. Thus, when industry members voluntarily change their labels, it is appropriate that they respond to any new requirements that have been published as final regulations up to that time. On the other hand, if any industry members can foresee that the proposed effective date will create particular problems, they should bring these problems to the agency's attention in comments on this proposal.

V. Analysis of Impacts

A. Executive Order 12866

FDA has examined the impacts of this proposed rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the 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 effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this proposed rule is neither an economically significant nor 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.

1. Options

FDA has assessed the costs and benefits of the following regulatory alternatives: Take no action, take the proposed action, or establish a common or usual name only for crabmeat derived from blue crab.

2. Benefits and Costs

a. *Option one: Take no action*. By convention, the option of taking no action is the baseline in comparison with which the costs and benefits of the other options are determined. Therefore, neither costs nor benefits are associated with taking no action.

b. *Option two: Take the proposed action*.

i. *Benefits*. The benefit of the proposed action is that consumers will be able to more easily identify the species source of crabmeat for which this proposed rule establishes common or usual names. The value consumers place on being able to more easily identify crabmeat derived from these species of crab is not known. However, in general terms, if consumer valuation of crabmeat differs widely by species, and consumers cannot differentiate those species in the absence of the proposed common or usual name regulations, then consumers will derive greater benefit from the establishment of the proposed common or usual names. If, in addition, consumers assume that products labeled simply as containing crabmeat contain a particular and relatively valuable species of crab, then the proposed common or usual names will protect consumers from the economic fraud associated with the substitution of crabmeat derived from a less valuable species of crab for that crabmeat derived from the more valuable species of crab. On the other hand, if consumer valuation of crabmeat does not differ widely by species, or if consumers can already differentiate species, e.g., because they are already labeled in a manner consistent with the proposed common or usual name regulations, then consumers will place relatively little value on the establishment of the proposed common or usual names.

FDA requests information about the following: Whether consumers can differentiate crabmeats derived from different species of crabs and, if so, how; whether consumers assume that products labeled simply as containing crabmeat contain a particular species of crab; and whether consumers place different values on crabmeats derived from different species of crabs. The agency also is interested in pricing data for crabmeat from different species. In particular, the agency is interested in data that takes into account seasonal availability and other factors that complicate price comparisons. The agency also requests information from consumers, crabmeat packers, and crabmeat product distributors about their experiences with species substitution practices, that is, where a less valuable crabmeat is substituted for a more valuable crabmeat.

ii. *Costs*. The primary social cost of the proposed action is the cost of changing the labels of crabmeat products that are not already labeled in a manner consistent with the proposed common or usual names. Depending on market conditions, these costs may be borne by crabmeat processors, packers, or repackers or may be passed on to consumers in the form of higher prices. This rule may also produce distributive effects, that is, this rule may make some firms and regions better off and some firms and regions worse off.

Labeling costs were estimated using a model developed for that purpose by Research Triangle Institute (RTI) under contract to FDA. The model allows one to estimate labeling costs based on the length of the compliance period, the complexity of the labeling change, and the Standard Industrial Code (SIC) classifications of the affected firms. The resulting labeling costs were comprised of administrative, redesign, and inventory costs. Total labeling costs are calculated by multiplying administrative costs by the number of affected firms and by multiplying redesign and inventory costs by the number of affected product lines, or Stock Keeping Units (SKU's). SKU's

differ from one another on the basis of either product formulation or packaging.

The proposed effective date is the next uniform effective date for labeling regulations following the publication of a final rule based on this proposal. This effective date will provide a compliance period of at least 1 year. The relevant SIC codes appear to be 2091, Canned and Cured Fish and Seafoods, and 2092, Fresh or Frozen Packaged Fish. The complexity of the required labeling changes depends on the current labeling of the affected products. If these products are currently labeled in such a way that only the ingredient list needs to be changed, then the required labeling changes will be relatively simple. If these products are currently labeled in such a way that both the ingredient list and the principal display panel must be changed, then the required labeling changes will be relatively complex. FDA has insufficient information on the current labeling of these products to estimate the proportion of products requiring label changes of different levels of complexity. Therefore, labeling costs will be estimated both for the case in which all affected products require only changes to the ingredient list and for the case in which all affected products require changes to both the ingredient list and the principal display panel. Actual labeling costs should fall somewhere between these two estimates.

The number of firms potentially affected by the proposed rule was determined using two data sources. These data sources differ with respect to data collection techniques, the frequency with which the data are updated, and so forth. Evaluation of the strengths and weaknesses of these data sources would be quite complex. Therefore, both data sources have been used.

One data source used to estimate the number of potentially affected firms was the Duns Market Identifiers data base. A search of this data base identified 108 establishments associated with 92 firms that appear to produce crab products of the type that would be affected by this proposed rule. In this case, the search procedure involved identifying establishments with either SIC 2091 or 2092 as their primary or secondary activity and having the word ''crab,'' but not the word ''imitation,'' in the description of their activity. The number of firms associated with these establishments was determined by further limiting the search to single establishment firms or headquarters of multiestablishment firms.

The other data source used to estimate the number of potentially affected firms was FDA Official Establishment Inventory (OEI). The OEI is a list of all establishments known to FDA.

A search of the OEI identified 594 establishments that are listed as either manufactures of crab products or crab repackers and that, therefore, could be affected by the proposed rule. Based on FDA experience, most of these plants probably represent independent firms. Based on these two data sources, the number of firms that might be affected by the proposed rule is estimated to be in the range of 92 to 594 firms.

The potential number of SKU's involved was estimated using the average number of distinct items per brand for crab products listed in the A. C. Nielsen Co. SCANTRACK Market Planner data base. This data base listed 210 brands and 346 items, for an average of 1.6 items per brand. Items are defined with respect to both product formulation and package size and, therefore, should correspond to SKU's. This average number of items or SKU's per brand was then multiplied by the estimated range of potentially affected firms to get a range of potentially affected SKU's. This procedure assumes that each firm is associated with only one brand name. Although some large firms may produce products under multiple brand names, the assumption of one brand name per firm is probably reasonable for most firms. Under these assumptions, the number of potentially affected SKU's is estimated to be between 147 and 950.

Some of the firms and SKU's that are potentially affected by the proposed rule might not actually be affected. In particular, some firms producing crab products might produce products containing only those nine species of crab for which common or usual names are already required by § 102.50. The products produced by these firms would not require label changes. In addition, some of the firms producing products containing species of crab for which common or usual names are being proposed might already be using the proposed common or usual name, which would be consistent with existing FDA labeling guidance provided in ''The Seafood List.'' Label changes would also not be required for these products. However, information is not available on the number of products that meet either of these conditions. To address the uncertainty generated by the absence of information on this issue, labeling costs will be estimated as a range with the low end of the range set to $0. Although it is unlikely that no products would require label changes, and that the cost of relabeling would actually be $0, it is possible that only a few products may need to be relabeled, and that relabeling costs might be quite low.

For a compliance period of 1 year, the RTI labeling cost model estimates the administrative costs for changing only the ingredient list and for changing both the ingredient list and the principal display panel to be $850 per firm for firms having fewer than 10 employees and to be $6,300 per firm for firms having 10 or more employees. Administrative costs are the same for firms in both SIC 2091 and 2092. With respect to firms listed in the Dun's Market Identifiers data base, 23 of the 92 firms are identified as having fewer than 10 employees. Data on the number of employees is not available for firms listed in the OEI. In the absence of other information, it is reasonable to suppose that the proportion of firms listed in the OEI that have fewer than 10 employees is the same as the proportion of firms listed in Dun's Market Identifiers. Under this assumption, 149 of the 594 firms listed in the OEI would have fewer than 10 employees. Based on these data and assumptions, total potential administrative costs are estimated to between $0.5 million and $3 million. Taking into account the fact that some potentially affected products may not contain the relevant species of crab or may already be labeled appropriately, administrative costs are estimated to be between $0 and $3 million.

For a compliance period of 1 year, the RTI labeling cost model estimates combined redesign and inventory costs for changing the ingredient statement only to be $290 per SKU for firms in SIC 2091 and $714 per SKU for firms in SIC 2092. That model estimates combined redesign and inventory costs for changing the ingredient statement and the principal display panel to be $1,740 per SKU for firms in SIC 2091 and $4,284 per SKU for firms in SIC 2092. Based on data from Dun's Market Identifiers, 17 potentially affected number are listed in SIC 2091, 62 firms are listed in SIC 2092, and 13 firms are listed in both. For the purposes of estimating costs, it seems reasonable to distribute the 13 firms that are in both SIC classes to one of the two relevant SIC classes in the same proportion as the firms found in only one of the relevant SIC classes. Under this assumption, 20 potentially affected firms would be found in SIC 2091 and 72 affected firms would be found in SIC 2092. Based on 1.6 SKU's per firm, this implies that the number of potentially affected SKU's in SIC 2091 is 32 and the

number of potentially affected SKU's in SIC 2092 is 119.

The OEI does not list firms by SIC. Therefore, it seems reasonable to suppose that the proportions of the relevant firms in SIC 2091 and SIC 2092 are the same as the proportions of the relevant firms in Dun's Market Identifiers. Under this assumption, 128 of the potentially affected 594 firms listed in the OEI would be in SIC 2091 and 466 of those firms would be in SIC 2092. Based on 1.6 SKU's per brand name, this implies that the number of potentially affected SKU's in SIC 2091 is 211 and the number of potentially affected SKU's in SIC 2092 is 768.

Based on the estimated number of potentially affected SKU's using Dun's Market Identifiers and the OEI, total potential redesign and inventory costs are estimated to be between $0 and $1 million for changing the ingredient statement only and between $1 million and $4 million for changing both the ingredient statement and the principal display panel. Taking into account the fact that some potentially affected products may not contain the relevant species of crab or may already be labeled appropriately, redesign and inventory costs are estimated to be between $0 and $4 million. Total labeling costs, including administrative, redesign, and inventory costs, are estimated to be between $0 and $7 million.

Labeling costs will be higher if some crabmeat products are currently made using any one of a number of species of crab. In that case, this proposed rule would require multiple product labels to be printed for products that currently use only one generic ''crabmeat'' label. Additional costs will be generated if compliance with the proposed labeling requirements involve other changes to the current method of manufacturing crabmeat products. However, FDA is not aware of any such costs. It should be noted that products may continue to be made with blends or mixtures of crabmeats, provided that each crabmeat in the blend or mixture is identified with its common or usual name. FDA requests information on the degree to which different crabmeats are used in the same products, and on any costs that may be generated by this proposed rule, including labeling, manufacturing, storage, and recordkeeping costs.

In addition to social costs, there may be distributive effects associated with establishing the proposed common or usual names because the labeling changes necessitated by common or usual names may increase the demand for certain species of crab and decrease the demand for other species of crab. In some cases, these changes in demand will simply reflect preexisting differences in the value consumers place on the different species of crab. However, in other cases, these changes in demand might result from adverse consumer attitudes towards certain of the proposed common or usual names. For example, some consumers might find the name ''Spider crabmeat'' unappealing, creating an aversion to Spider crabmeat that did not previously exist. Distributive effects caused by adverse consumer attitudes toward certain of the proposed common or usual names would ordinarily be considered a greater cause of concern than distributive effects caused by preexisting consumer preferences for different species of crab. FDA has insufficient information to estimate changes in the demand for various species of crab or to determine the degree to which any changes in demand reflect either preexisting preferences or consumer attitudes toward the words used in the proposed common or usual names. FDA requests information on the distributive effects of this rule. In addition, FDA requests information on whether any of the proposed common or usual names might reduce the demand for a particular species of crab for reasons unrelated to preexisting preferences for that species of crab.

c. *Option three: Establish a common or usual name only for blue crabmeat.*

i. *Benefits.* FDA cannot estimate the difference in the benefits of this option relative to the benefits of taking the proposed action because FDA does not have information on the value consumers place on blue crabmeat relative to crabmeat from other species of crab, the degree to which consumers can already differentiate products that contain blue crabmeat from products that contain crabmeat from other species of crab, or the degree to which consumers assume that products labeled as ''crabmeat'' contain blue crabmeat. FDA requests public comment and information on these issues.

ii. *Costs.* The costs associated with this option would be less than the costs associated with taking the proposed action because this option would affect only a subset of the products that would be affected by the proposed action. Therefore, estimated labeling costs would be less than $7 million and any other costs associated with the proposed action would also be less than they would be under the proposed action. FDA cannot estimate the difference in costs more precisely because FDA has information only on the number of products that contain crabmeat, not on the number of products than contain blue crabmeat. FDA requests information on the number of products containing exclusively blue crabmeat or on the proportion of all crabmeat-containing products that contain blue crabmeat.

B. Analysis of Impacts on Small Businesses

FDA has examined the impacts of this proposed rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (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. FDA finds that this proposed rule, if issued, might have a significant impact on a substantial number of small entities.

1. Options

FDA has assessed the impacts on small entities of the following regulatory alternatives:

Take no action, take the proposed action, or establish a common or usual name only for crabmeat derived from blue crab.

a. *Option one: Take no action.* Taking no action would have no impact on small businesses.

b. *Option two: Take the proposed action.* As discussed in the Executive Order 12866 analysis, the primary cost of taking the proposed action is the cost of changing the labels of products that contain the relevant species of crab and that are not already labeled in a manner consistent with the proposed common or usual names for those species. This cost was estimated to be between $0 and $7 million for all firms. The Small Business Administration's definition of a small business for the SIC codes identified as relevant in the Executive Order 12866 analysis, SIC codes 2091 and 2092, is a firm having 500 or fewer employees. Under this definition, 88 of the 92 firms identified in the Dun's Market Identifiers data base as potentially affected by this proposed rule are small businesses. As indicated previously, the OEI does not contain information on the number of employees.

Based on this information, it is likely that some portion of the costs estimated for all firms will be borne by small businesses. A more precise estimation of the proportion of estimated total costs borne by small firms would require information that is not currently available on the average difference in the number of SKU's (products and product sizes) produced by large and small firms. The estimated costs could be significant for some small firms.

However, only relatively modest cost reductions would be produced by further lengthening the compliance period, and any level of cost could be significant for some small firms.

With respect to the distributive effects discussed in the benefit-cost analysis of this option, FDA has no information to suggest systematic differences in the species of crabs used by small and large firms. Therefore, FDA has no reason to suspect that any distributive effects will have a net negative effect on small firms as a class of firms. Of course, some of the firms that may be negatively affected by distributive effects may be small firms.

c. *Option three: Establish a common or usual name for blue crab only* This option would reduce the impact of this proposed rule on small businesses because this option would affect only a subset of the products that would be affected by taking the proposed action. FDA cannot estimate the reduction of the impact on small businesses for two reasons. First, FDA has information only on the number of products that contain crabmeat, not on the number of products than contain blue crabmeat. Therefore, FDA cannot determine the degree to which total costs would be reduced by this option. Second, FDA has information only on the number of small businesses that manufacture products containing crabmeat, not on the number of small businesses that manufacture products containing blue crabmeat. Therefore, FDA cannot determine the proportion of the total cost reduction that would accrue specifically to those small businesses that manufacture crabmeat products without blue crabmeat. FDA requests information on the number of products that contain blue crabmeat and the number of small businesses that produce products containing blue crabmeat. FDA also requests information on the number of products that contain crabmeat from other species of crab, and the number of businesses and small businesses that produce products containing crabmeat from other species of crab. Finally, FDA also requests information on other alternatives that might reduce the burden of this proposed rule on small businesses.

VI. Environmental Impact

The agency has determined under § 25.30(k) (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. The purpose of the proposed rule is to ensure that consumers are informed about the identity of all crabmeats, and this will not change the intended use of this food product. The proposed action is not expected to increase the demand for blue crabmeat because the competition in the marketplace between blue crabmeat and lower priced crabmeat from other species of crabs can be expected to control the demand for blue crabmeat. However, because the impact of this proposed rulemaking on consumer demand for blue crabmeat is uncertain, FDA solicits public comment on any adverse effects the proposed labeling provisions may have on blue crab populations. The agency will evaluate its tentative conclusion that the proposed action warrants a categorical exclusion under § 25.30(k) in light of any relevant comments responding to this proposal.

VII. References

The following references have been placed on display in 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. Williams, Austin B., Lawrence G. Abele, et al., ''Common and Scientific Names of Aquatic Invertebrates from the United States and Canada: Decapod Crustaceans,'' American Fisheries Society Special Publication 17, pp. 41, 1989.

2. Organization for Economic Cooperation and Development, ''Multilingual Dictionary of Fish and Fish Products,'' 3d ed., Fishing News Books, pp. 63, 1990.

3. Krane, W., ''Five-Language Dictionary of Fish, Crustaceans and Molluscs,'' Van Nostran Reinhold, pp. 32, 1986.

4. Letter to the District Director, U.S. Customs Service, Department of the Treasury, from Harvy B. Fox, Director, Office of Regulations and Rulings, U.S. Customs Service, Department of the Treasury, Washington DC, regarding ''Country of Origin Marking of Canned Crabmeat,'' August 6, 1989.

5. AOAC Official Methods of Analysis 980.16 Identification of Fish Species, Thin Layer Polyacrylamide Gel Isoelectric Focusing Method, p. 885, 1990.

VIII. Comments

Interested persons may on or before July 7, 1998, 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.

List of Subjects in 21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Oils and fats, Onions, Potatoes, Seafood.

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 102 be amended as follows:

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

1. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 371.

2. Section 102.50 is revised to read as follows:

§ 102.50 Crabmeat.

The common or usual name of crabmeat derived from each of the following designated species of crabs shall be as follows:

Common or usual name of crabmeat	Scientific name of crab
Blue crabmeat	*Callinectes sapidus.*
Brown King crabmeat	*Lithodes aequispina.*
Centolla crabmeat	*Lithodes antarcticus* and *Lithodes murrayi.*
Deepsea crabmeat	*Paralomis granulosa.*
Dungeness crabmeat	*Cancer magister.*
Golden crabmeat	*Geryon fenneri.*
Jonah crabmeat	*Cancer borealis.*
King crabmeat	*Paralithodes camtschaticus* and *Paralithodes platypus.*
King crabmeat or Hanasaki crabmeat	*Paralithodes brevipes.*
Korean variety crabmeat or Kegani crabmeat	*Erimacrus isenbeckii.*

Common or usual name of crabmeat	Scientific name of crab
Lithodes crabmeat	*Neolithodes brodiei.*
Red crabmeat	*Geryon quinquedens.*
Rock crabmeat	*Cancer irroratus* and *Cancer pagurus.*
Snow crabmeat	*Chionoecetes angulatus*, *Chionoecetes bairdi*, *Chionoecetes opilio*, and *Chionoecetes tanneri.*
Spider crabmeat	*Jacquinotia edwardsii* and *Maja squinado.*
Stone crabmeat	*Menippi adina* and *Menippi mercenaria.*
Swimming crabmeat	*Callinectes arcuatus*, *Callinectes toxotes*, *Portunus pelagicus*, and *Portunus puber.*

Dated: April 17, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–10743 Filed 4–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–121268–97]

RIN 1545–AW10

Travel and Tour Activities of Tax Exempt Organizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations clarifying when the travel and tour activities of tax exempt organizations are substantially related to the purposes for which exemption was granted. These proposed regulations are intended to augment the guidance that currently exists with respect to travel tours and the unrelated business income tax.

DATES: Written comments and requests for a public hearing must be received by July 22, 1998.

ADDRESSES: *Send submissions to:* CC:DOM:CORP:R (REG–121268–97), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. *Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to:* CC:DOM:CORP:R (REG–121268–97), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS internet site at http://www.irs.ustreas.gov/prod/tax__regs/comments.html.

FOR FURTHER INFORMATION CONTACT: Robin Ehrenberg, (202) 622–6080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

An organization generally exempt from tax under section 501(a) of the Internal Revenue Code (''Code'') must pay tax on its unrelated business taxable income, as defined in section 512. Section 512(a)(1) defines unrelated business taxable income (''UBTI'') as the gross income derived by any organization from any unrelated trade or business (as defined in section 513) regularly carried on by the organization, less the deductions which are directly connected with the conduct of the trade or business. Gross income from an unrelated trade or business and any deductions directly connected to that trade or business are both computed in accordance with the general income tax rules of chapter 1 of the Internal Revenue Code, subject to the modifications provided in section 512(b).

Section 513(a) generally defines an unrelated trade or business as any trade or business the conduct of which is not substantially related (aside from the need of an organization for income or funds or the use it makes of the profits derived) to the exercise or performance by the organization of its charitable, educational, or other purpose or function constituting the basis for its exemption under section 501.

A ''trade or business'' is defined in Section 1.513–1(b) of the Income Tax Regulations as having the same meaning it has for purposes of section 162, and ''generally includes any activity carried on for the production of income from the sale of goods or performance of services.'' The key test of whether an activity constitutes a trade or business is whether the activity was conducted with a profit motive. See *U.S.* v. *American Bar Endowment,* 477 U.S. 105 (1986); *Professional Insurance Agents of Michigan* v. *Commissioner* 726 F.2d 1097 (6th Cir. 1983); *National Water Well Association* v. *Commissioner,* 92 T.C. 75 (1989). The regulations further provide that an activity conducted for the production of income does not lose its character as a business ''merely because [it is] carried on within a larger aggregate of similar activities or within a larger complex of other endeavors which may, or may not, be related to the exempt purposes of the organization.'' This ''fragmentation rule,'' as it is commonly known, may result in different treatment of related activities under the unrelated business income tax.

Section 1.513–1(d)(2) of the Income Tax Regulations provides that a trade or business is ''substantially related'' to exempt purposes only where the conduct of the business activities has a substantial causal relationship to the achievement of the exempt purposes (other than through the production of income) of the organization conducting the trade or business. Thus, a trade or business is substantially related for purposes of section 513 only if the conduct of the trade or business contributes importantly to the accomplishment of the organization's exempt purposes.

In recent years, taxpayers and Congress have asked the IRS to publish guidance addressing questions relating to the unrelated business income tax treatment of income generated from travel tours conducted by tax exempt organizations. Although the IRS has issued a number of revenue rulings addressing situations in which tax exempt organizations sponsor travel tours, most of these rulings have analyzed whether an organization that offers travel tours as its primary activity can qualify as a charitable or educational organization described in section 501(c)(3) of the Code.

Rev. Rul. 67–327, 1967–2 C.B. 187, holds that an organization whose purpose is to arrange group tours for students and faculty of a university in order to allow them to travel abroad does not qualify for exemption because the organization operates essentially as