ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

July 27, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, MD 20857

Dear Dr. von Eschenbach,

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating questions regarding the ability and the will of the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) to protect Americans from contaminated and otherwise unsafe items in our food supply. On February 9, 2006, we wrote you regarding the series of related decisions by the Center for Food Safety and Applied Nutrition (CFSAN) to permit the use of carbon monoxide (CO) to alter the color of meat and fish to make those products appear fresh, safe, and wholesome, regardless of their actual condition and well beyond the time when they may be safe to consume.

We remain seriously concerned about the public health risks of this deceptive practice, particularly in light of information regarding imported fish delivered in CO containing packaging that has been rejected as unfit for human consumption. We understand that 20 percent of such fish imports tested have been rejected by the FDA laboratory in San Francisco since the practice was first discovered. If the regulatory authorities at CFSAN were aware of these findings and still determined that meat and fish so deceptively packaged should be considered "Generally Recognized As Safe" (GRAS) then something is seriously and dangerously amiss in the Center.

Even before we became aware of degraded fish imports, we were at a loss to understand how FDA could have disregarded established law by accepting GRAS notifications from companies seeking FDA approval, permitting the use of carbon monoxide to preserve the red color of fresh meat, despite the meat's age or conditions under which it has been held. We find it particularly troubling that FDA made this decision behind closed doors, rather than through the public notice and comment process that should have been employed. We request FDA's

responses to the following questions to clarify the agency's decision-making process in this matter.

1. Color Additive: Precept Foods, LLC (Precept) submitted a GRAS notification to FDA regarding its use of carbon monoxide in modified atmosphere packaging (MAP) for fresh meat. Precept's GRAS notification (GRN 000143) makes clear that the carbon monoxide in its packaging system functions to make the meat appear to have the red color associated with fresh, wholesome meat indefinitely, as long as the meat remains in the package. Upon receiving Precept's purported GRAS notification, did FDA consider that the carbon monoxide in the Precept MAP system was a color additive and therefore not eligible for GRAS status? If not, why not?

   Please provide all documents, including but not limited to, internal agency and inter-agency communications as well as external communications, relating to the legal determination that carbon monoxide in the Precept MAP system is not a color additive.

2. Safety Considerations: FDA is responsible for determining whether the use of carbon monoxide in fresh meat is safe. It is well recognized that regardless of the age of the meat or whether it has been temperature-abused, carbon monoxide masks the visual signs of microbial spoilage.

   a. Was the safety risk associated with carbon monoxide's ability to mask indicators of microbial spoilage in fresh meat addressed in FDA's review of this use of carbon monoxide? If not, why not?

   b. In particular, did FDA consider the safety implications of consumption by at-risk populations such as the elderly, children, pregnant women, persons taking immunosuppresent drugs, or AIDS patients of apparently fresh looking meat containing high levels of bacteria ($>1x10^7$ colony forming units per gram)?

3. GRAS Standard: FDA's GRAS standard requires that there be consensus among qualified experts that a substance is safe for its intended use. FDA has advised that the "common knowledge" element of the GRAS standard generally requires that such consensus be documented through scientific data and information in the published literature, and that "an ongoing scientific discussion or controversy about safety concerns raised by available data would make it difficult to provide a basis for expert consensus about the safety of a substance for its intended use."

   We are aware of a number of published studies that have raised or acknowledged questions about the safety of carbon monoxide in fresh meat packaging because its coloring effect can mask signs of spoilage, e.g., Sørheim (1997 & 1999), Kropf (1980). Most significantly, the European Commission's Scientific Committee on Food observed that the use of carbon monoxide would be safe only if the temperature during storage and

transport never exceeds 4°C (39°F). Recognizing the realities of temperature abuse and, therefore, the likelihood that carbon monoxide's coloring effect would mask spoilage, the European Parliament banned this use of carbon monoxide in fresh meat.

Most importantly, FDA documents provided to the Committee and interviews by Committee staff of FDA laboratory and other field personnel in San Francisco and New York, clearly show that the agency knew that fish unfit for human consumption was imported in atmospheres containing carbon monoxide. Disregarding the data from its inspections, FDA decreed that fish and, later, meat treated with CO were GRAS. In fact, the agency issued an Import Bulletin on "Tuna Processed with Tasteless Smoke and/or Carbon monoxide" on May 27, 1999, that "responds to numerous complaints that FDA has received on the importation of tuna that has been processed with 'tasteless smoke'(TS) or carbon monoxide." It is our understanding that carbon monoxide is the coloring agent in "tasteless smoke."

Furthermore, FDA e-mails and other documents indicate the agency was well aware of the problem to many species including tuna. In fact, the agency required importers of all fish products that arrived in an atmosphere of carbon monoxide to identify the CO on the labeling and import documents.

a. Given the agency's own experience with contaminated, decomposed imported fish appearing fresh and wholesome because of carbon monoxide coloring, please explain how FDA concluded that this use of carbon monoxide in fresh meat packaging is deemed GRAS.

b. Given the documented controversy and the European ban due to safety concerns, please explain how FDA analyzed this scientific literature under its GRAS standard and concluded that meat and fish treated with CO is "Generally Recognized As Safe."

c. Did FDA consider the need for a food additive petition for the use of carbon monoxide in fresh meat packaging? If not, why not?

Please provide all documents, including internal agency communications and notes that were not provided to the Committee in response to our February 9, 2006 request, addressing whether the data and information in the Precept GRAS notification satisfied FDA's GRAS standard. In particular, please provide all documents relating to the agency's consideration of the European ban, if any.

Please also provide all records relating to the determination that fish processed using "tasteless smoke" or carbon monoxide is GRAS.

4. Consumer Reliance on Meat Color: It is well documented in published scientific and industry literature that consumers rely heavily upon meat color when selecting fresh meat for purchase and consumption. Indeed, the sole purpose for including carbon monoxide in fresh meat MAP is to give the meat the red color consumers prefer.

    a. Did FDA recognize that consumers would presume that the bright red color of carbon monoxide-treated meat was a sign that the meat was fresh and safe to eat?

    b. Did FDA solicit from Precept or obtain from any other source, consumer perception data, to determine whether the unlabeled use of carbon monoxide could induce consumers to purchase and consume meat that is no longer fresh and may not be fit for human consumption? If not, why not?

    c. If FDA believes that color is not an ideal measure of meat freshness and safety, how would the agency advise consumers to select meat packaged in sealed MAP?

    d. Does FDA plan to conduct a consumer education campaign to train consumers away from their traditional reliance on meat color and appearance?

    Please provide all documents relating to FDA's consideration of consumer behavior in meat selection during the course of its review of the GRAS notifications for the use of carbon monoxide in fresh meat packaging. Please also provide all documents, including but not limited to, all internal notes or other memoranda, as well as correspondence with USDA's Food Safety and Inspection Service (FSIS), reflecting FDA's and FSIS's consideration of the ability of carbon monoxide to conceal the true freshness, quality, and safety of meat.

5. Odor as a Spoilage Indicator:

    a. FDA has stated that consumers should use odor rather than color as an indicator of meat freshness and safety. Please explain how FDA addressed the fact that odor cannot be detected when purchased because the meat is sealed in MAP, and that governing law focuses on and prohibits adulteration and deception at the time of purchase.

    a. The National Geographic Survey (NGS), in a seminal work involving 1.2 million subjects, found that chemical exposure, pregnancy, head injury, and colds and flu can cause permanent loss of smell, but overwhelmingly, such loss occurs as we age. As one article by prominent nutritionists noted, after reviewing the NGS findings, "the decline in sensitivity to the odor with age is large enough to render the odor useless as a warning for about half of the elderly population." The scientific literature also documents olfactory dysfunction among cancer patients, particularly among those undergoing chemotherapy or radiation. Did FDA

consider the sizable portion of the population whose sense of smell may be impaired, particularly among those who may also be most vulnerable to food borne illness because of impaired immune systems? If not, why not?

6. Date Labeling:

   a. FDA has stated that "use or freeze by" date labeling will provide information to consumers sufficient to ensure the safe use of carbon monoxide in fresh meat. Please provide all consumer behavior research or other evidence that supports this assertion, whether submitted in GRAS notifications or obtained independently by FDA.

   b. Does FDA impose any prominence requirements to ensure that such "use or freeze by" date labeling is appropriately read and understood by consumers so that the inclusion of carbon monoxide in fresh meat MAP does not render the meat unsafe? If not, why not?

7. Temperature Abuse: Temperature abuse in meat storage and distribution channels, at retail, and in the refrigerators of consumers, has been widely documented—in published scientific literature, in FDA's Food Code, by FSIS, and in media exposés. Such temperature abuse generally causes meat, not treated with carbon monoxide, to turn brown rapidly. This has historically signaled to consumers that the meat may not have been held under appropriate conditions and may not be safe to consume. Fresh meat treated with carbon monoxide, however, will remain bright red regardless of temperature abuse.

   a. To the extent that FDA considered "use or freeze by" date labeling sufficient to ensure the safe use of carbon monoxide in fresh meat, did the agency consider the fact that temperature abuse would render such date labeling meaningless as an assurance of meat freshness and safety?

   b. Was FDA's consideration of the GRAS status of carbon monoxide in fresh meat packaging limited to information about use of carbon monoxide under laboratory conditions of ideal temperature control? If so, please explain why FDA disregarded the known prevalence of temperature abuse.

   c. Did FDA recognize that the fear of economic loss associated with meat "browning" has historically provided a strong incentive to assure adequate temperature control of meat throughout the chain of distribution, storage, and retail sale, and that such incentives would be eliminated by this use of carbon monoxide, which conceals evidence of mishandling?

8. Shelf life: As a condition of the safe use of carbon monoxide in fresh meat packaging, FDA accepted "use or freeze by" date labeling of up to 35 days following the date of packaging for intact muscle cuts and up to 28 days for ground beef. The documents supporting Precept's GRAS notification appear to indicate that these shelf lives were established under laboratory conditions reflecting ideal temperature control. Even Precept, the original proponent of the 35- and 28-day shelf lives, has stated that it would employ "more conservative dates," reflecting a shorter shelf life.

    a. How did FDA determine that the 35- and 28-day labeled shelf lives would be adequate to assure the safety and wholesomeness of carbon monoxide-treated meat under actual conditions of distribution, storage, retail sale, and consumer handling?

    b. Given that the European Commission's Scientific Committee on Food concluded that carbon monoxide-treated meat could have a shelf life of 14 days for beef loin steaks and 11 days for ground beef, how did FDA conclude that carbon monoxide-treated meat with shelf lives up to 35 or 28 days was "Generally Recognized As Safe"?

9. FDA Regulatory Prohibition of Carbon Monoxide in Fresh Meat: FDA's food additive regulation for combustion products gas (21 C.F.R. 173.350) appears to prohibit the use of carbon monoxide on "fresh meat products." In a February 13, 2002 letter to FDA regarding the Pactiv GRAS notification, FSIS apparently endorsed this view "because of concerns that the treatment of meat with combustion product gases may cause the meat to retain its fresh red color longer than meat not so treated, thereby misleading the customer, and increasing the potential for masking spoilage." Carbon monoxide is the only combustion product gas that affects meat color deceptively.

    Please explain whether FDA now disagrees with its own regulation at 21 C.F.R. 173.350 or considers it no longer operative. If so, why has FDA not addressed the matter through notice and comment rulemaking?

10. Labeling: FDA accepted the use of carbon monoxide in the Precept MAP system without requiring carbon monoxide to be labeled, although it is apparently still required for tuna. Under governing law and FDA regulations, policy, and precedent, however, there is no regulatory category into which this use of carbon monoxide could fall that would not require it to be labeled. As noted above, the use of carbon monoxide in fresh meat meets the statutory definition of a color additive, which must be labeled under 21 U.S.C. 343(k) and 21 C.F.R. 101.22(k). Even if FDA considers carbon monoxide in fresh meat to be GRAS (or a food additive), it would appear to be a functional ingredient in the meat that must be declared on the label.

a. Please explain how this use of carbon monoxide differs from FDA's regulatory example of chemical preservatives used "to promote color retention," which must be labeled under 21 U.S.C. 343(k) and 21 C.F.R. 101.22(j).

b. Please explain why the use of carbon monoxide in fresh meat packaging, which makes the meat red indefinitely, regardless of age or temperature abuse, does not need to be disclosed on the label, as would appear to be the case to comply with 21 U.S.C. 343(a) and 321(n).

11. Processing Aids Exempt from Labeling: FDA regulations provide that substances may qualify as "processing aids" and therefore be exempt from ingredient labeling requirements only if, in relevant part, the substances "are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food" (21 U.S.C. 101.100[a][3][ii][*c*]). In the Precept system, the carbon monoxide remains functional in the retail package to make the meat appear red indefinitely. Did FDA deem the carbon monoxide in the Precept MAP system to be a processing aid? If so, please explain how the carbon monoxide in that system satisfies FDA's regulatory definition of a processing aid.

    Please provide all records, including but not limited to, internal notes, memoranda, and communications with Precept and FSIS, addressing labeling of the carbon monoxide in Precept's MAP system, including whether it met FDA's definition of a processing aid. To the extent not otherwise requested, please provide all records, including but not limited to, internal notes, memoranda, and inter-agency communications relating to all contacts with FSIS personnel regarding GRN 000143.

12. Carbon Monoxide in Tuna: In response to GRAS Notification No. GRN 000015, FDA accepted the use of "tasteless smoke," of which carbon monoxide is a primary component, as a preservative to protect the taste, aroma, and color of fresh tuna prior to freezing. FDA required the presence and purpose of tasteless smoke to be declared on the labels of treated tuna. The use of carbon monoxide/tasteless smoke was addressed in a recent Congressional Research Service (CRS) Report for Congress entitled, "Seafood marketing: Combating Fraud and Deception, April 11, 2007." CRS reports that this use of carbon monoxide or "tasteless smoke" has alarmed consumer advocates, who say it deceives shoppers who depend on color to help them avoid spoiled fish, and more broadly, noted serious concerns about FDA's enforcement of seafood labeling requirements.

    a. Did FDA consider the labeling requirements for "tasteless smoke" to be a sufficient safeguard to ensure that the use of carbon monoxide/"tasteless smoke" did not deceive consumers into purchasing or consuming tuna that may have become unsafe while remaining fresh-looking?

b. If so, what steps has FDA taken to ensure that treated tuna is consistently and appropriately labeled, whether it is pre-packaged or sold by weight in the retail fish case, so that consumers are not deceived by tuna that may appear fresher or safer than it is?

We remain seriously concerned that FDA's allowance of the use of carbon monoxide to conceal the true freshness and safety of meat and fish has placed the public health at risk. Amid the spate of recent food recalls and food safety incidents, including a number of recalls due to *E. coli* in ground beef, confidence in FDA's ability to assure a safe food supply has been eroding. The unexplained departure from established food safety law and precedent in allowing the use of carbon monoxide in fresh meat, agreed to behind closed doors, does not help inspire confidence in the agency. If FDA still asserts that the use of carbon monoxide to color fresh meat and/or fish does not present a food safety risk, FDA should institute notice and comment rulemaking to permit these uses, as the law requires, and to inspire greater confidence in these suspect determinations.

Thank you for your attention to this public health matter and to our concerns. With regard to questions and related document requests made in this letter, we would appreciate your responses no later than the close of business August 10, 2007. If you have any questions regarding this request, please contact us, or have your staff contact David Nelson or Kevin Bartow of the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Michael O. Leavitt, Secretary
U.S. Department of Health and Human Services

Richard A. Raymond, Under Secretary for Food Safety
U.S. Department of Agriculture