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Center for Food Safety and
Applied Nutrition (CFSAN)
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Use of Carbon Monoxide (CO) in Case-Ready Fresh Meat Packaging; Docket No. 2005P-0459; Reply to Kalsec Comments

Dear Dr. Tarantino:

On behalf of our client, Precept Foods, LLC ("Precept Foods"), we are responding to the February 1, 2006 letter submitted by Kalsec, Inc. ("Kalsec") concerning the use of carbon monoxide (CO) in fresh meat packaging. 1/ A joint venture between Cargill Meat Solutions Corporation and Hormel Foods Corporation, Precept Foods markets case-ready fresh meat products in modified atmosphere packaging (MAP) systems that include low levels of CO (at a target concentration of 0.4%). As with the original petition, the most recent Kalsec submission continues to obscure the relevant laws, regulations, and agency precedent. We again urge the Food and Drug Administration (FDA) to deny the petition, which is simply a calculated attempt to discredit a competing technology.

1/ FDA Docket No. 2005P-0459 (Citizen Petition of Kalsec, Inc.) (Nov. 15, 2005).

2005P-0459 C6

As explained in detail in our January 23, 2006 letter, the use of CO in fresh meat packaging is generally recognized as safe (GRAS), lawful, and firmly rooted in agency precedent. FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) have properly reviewed this technology numerous times without objection. The Kalsec petition and subsequent submission provide—in over 40 pages of combined text, not including nearly 30 attachments—no information that credibly calls into question the safety or suitability of CO for use in fresh meat packaging. The two submissions are packed with exaggerations and information apparently intended to further Kalsec's public relations campaign and not to inform sound decision-making by FDA or USDA. In short, this campaign is an attempt to use the regulatory and legislative processes to address a competitive issue.

Significantly, case-ready systems are widely regarded as enhancing food safety and security, as such systems are produced in a central location under FSIS inspection, are marked with a validated "use-or-freeze by" date, and are subject to no further handling after manufacture. To date, the marketplace has not fully embraced the case-ready format because commonly used systems have quality and other disadvantages. Use of CO at trace levels, however, is gradually allowing industry to expand case-ready offerings in a meaningful way. In this era of limited agency resources, it is unfortunate that Kalsec's submissions will not only distract FDA from work on matters of true public health significance; the arguments being advanced are targeting innovations that can actually improve food safety and security for consumers by expanding the use of a safe and effective packaging format.

Critics of MAP systems with CO emphasize that consumers use color to select meat products. Indeed, consumers use appearance as a primary factor in selecting most foods. For meat products, appearance in terms of color is not an end in itself: the issue is whether the packaged product is wholesome and truthfully represented. The CO-containing systems presently in use start with and maintain wholesome products for a clearly identified shelf life. In the unlikely event of abuse, signs of spoilage (e.g., odor) will be present. This scenario is no different from vacuum-packaged meats or any of a number of foods with colors that remain stable while in a packaged form.

In the interest of efficiency, we will not attempt to repeat the detailed information provided in our initial comments. We believe, however, that the following points are worthy of emphasis:

- **Used at trace levels, CO is not a color additive—a substance "imparts color," and thus is a "color additive," only if it adds a visibly different, new color to food.** As we explained previously, the statute designates as "color additives" those substances capable of "imparting color" to food. FDA's 1980 decision on nitrites makes abundantly clear that a "practical, common sense approach" is to be used in assessing whether a substance "imparts color." 2/ The key issue is whether a substance is "capable of coloring food to a degree apparent to the naked eye," so that it changes color "in the ordinary sense of the term." 3/ As FDA explained in the case of nitrites—

  > [I]t is the addition of a visibly different, new color that makes a substance fall within the "color additive" definition. Substances that affect the color of food in other ways are regulated under other provisions of the act. 4/

  Substances cited by Kalsec, including hair dyes, tanning lotions, and feed additives that change the color of fish flesh from grey to pink, clearly "impart color" by changing the natural color of human hair, human skin, or food in a perceptible way. 5/ In contrast, a substance that stabilizes color does not, by definition, add a new or visibly

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2/ 45 Fed. Reg. 77043, 77045-77046 (Nov. 21, 1980). The 1980 *Federal Register* notice on nitrites is a key development in FDA's color additive precedent, particularly with respect to meat and poultry. It is of obvious and direct importance to all substances that stabilize product color, not simply nitrites.

3/ *Id.* at 77046.

4/ *Id.*

5/ A color change caused by cooking does not cause a substance to be regulated as a color additive. *Id.*

different color to food. 6/ Accordingly, under longstanding FDA and USDA precedent, a substance that stabilizes color under its intended conditions of use is NOT considered to "impart color" and therefore is NOT a "color additive."

- **The GRAS uses of CO stabilize meat color.** The use of CO at a target concentration of 0.4% in a modified atmosphere package does not change the natural color of meat, nor does it in any way result in an "artificially intense" color. The effect of CO at higher levels of use, such as 2%, is irrelevant to an intended use at much lower levels.

- **By law, "food additives," GRAS substances, and "color additives" must be equally safe.** The regulatory classification of a substance as a "food additive," "color additive," or GRAS substance is of no consequence to public health. All must be safe for their intended use. Indeed, FDA deemed a practical approach to its color additive jurisdiction prudent and necessary to "avoid wasteful disputes about the proper regulatory category" into which a substance should fall. 7/ Ironically, the agency's color additive precedent is now being twisted and misconstrued for precisely that purpose—a wasteful dispute designed to harm a competitive technology.

- **The Combustion Product Gas regulation does not apply.** Our January 23, 2006 letter explained in no uncertain terms why the regulation for "combustion product gas" does not apply to CO. Moreover, even if FDA were to consider the regulation to apply to

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6/ In assessing whether a color in fresh meat is "new" or "visibly different," the appropriate reference point is the color of bloomed meat packaged in ambient air. Thus, it makes no difference that meat packaged in a low oxygen environment without CO is purple. Indeed, if it did make a difference, then by that reasoning the oxygen used in high oxygen environments would also be a "color additive."

7/ 45 Fed. Reg. at 77045. FDA specifically explained that in enacting the Color Additive Amendments of 1960 "Congress and HEW (the Department that drafted the bill) . . . were aware . . . that all substances intentionally added to food would be subject to acceptably rigorous regulatory standards whether regarded as 'color additives' or not and that it was therefore unnecessary to make fine distinctions among substances based on such refined considerations as the precise nature of the chemical reaction that occurs when a substance is added to food." *Id.*

CO—which the agency has already explained to the press it does not—the plain language of that regulation does not in any way prohibit the use of CO in MAP systems for fresh meat. No amount of posturing or creative interpretation can change the plain meaning of a regulation, which is necessarily controlling as a matter of law.

- **There is no genuine scientific dispute as to the safety of CO in MAP systems for fresh meat under the conditions of intended use.** There is no "ongoing scientific discussion or controversy" concerning the key issue from a GRAS perspective—whether "there is a reasonable certainty in the minds of competent scientists" that the use of CO in fresh meat packaging "is not harmful under the intended conditions of use." 8/ As Kalsec now admits, the safety of low oxygen packaging systems is not disputed. Further, CO does not promote pathogen growth or otherwise affect the microbial characteristics of meat. 9/ Thus, a low oxygen package containing CO at low levels will

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8/ 21 C.F.R. § 170.3(i). The consensus element of the GRAS standard does not require unanimity: to preclude a GRAS determination, there must be a "severe conflict" among qualified experts; the existence of a "mere conflict" of expert opinion is not sufficient. 62 Fed. Reg. 18937, 18939 (Apr. 17, 1997). Moreover, fundamental questions of safety should not be confused with ongoing scientific discussions regarding optimal conditions of use. For instance, a scientific discussion regarding the optimal concentrations of MAP gases to inhibit pathogen growth does not call into question the GRAS status of carbon dioxide or nitrogen.

9/ At the levels used in fresh meat packaging, CO is not regarded as having any meaningful effect on the normal microflora of fresh meat. *See, e.g.,* O. Sørheim, et al., *The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide*, Meat Sci. Vol. 52, 157, 162 (1999) ("Our data suggest that 0.4% CO probably has little or no direct effect on the growth of bacteria.") (Attachment 1). The published literature also establishes that CO is not reasonably expected to selectively favor pathogen growth. *See* H. Nissen, et al., *Comparison between the growth of Yersinia enterocolitica, Listeria monocytogenes, Escherichia coli O157:H7 and Salmonella spp. in ground beef packed by three commercially used packaging techniques*, Int. J. Food Micro., Vol. 59, 211-220 (2000)(Attachment 2); J.H. Silliker and S.K. Wolfe, *Microbiological Safety Considerations in Controlled-Atmosphere Storage of Meats*, Food Tech. 59-63 (Mar. 1980)(Attachment 3). Although Nissen et al. found that *Salmonella* spp. grew under abusive conditions (10°C) to a higher number in ground beef packed in a high CO_2/low CO mixture than ground beef stored in high O_2, the authors noted that this finding was contrary to "many other studies" and possibly related to the "very low" numbers of competitive flora in the *Salmonella* experiment. Moreover, all such results must be kept in perspective: although every effort must be made to create a packaging environment that is not conducive to pathogen growth under normal or abusive conditions, the absence of an

function in the same manner as any other low oxygen package and will be equally safe. The only impact of CO is stabilization of the product color, which reflects oxidation and not the microbial safety or quality of meat.

- **CO-containing systems pose no unique hazards under abusive conditions.** Much of the criticism concerning the use of CO in the media and other non-scientific venues has focused on the performance of CO-containing MAP systems under abusive conditions. This criticism is misplaced. As we have explained previously, data in the literature and data generated by Precept Foods show that CO does not mask spoilage, so consumers will be able to judge whether a product has been temperature abused and is not suitable for consumption. Moreover, although Precept Foods considers the performance of its MAP systems under possible abuse conditions important—as Precept Foods produces branded products for consumers and must meet their expectations—an excessive emphasis on such conditions is inappropriate. The risk of temperature abuse, especially any alleged threat of deliberate mishandling in the distribution chain, is speculative and certainly not relevant to the intended or likely conditions of use for CO in fresh meat packaging. Indeed, similar allegations could be made with respect to many perfectly safe perishable foods (e.g., milk, eggs, processed and cured meats, fresh-cut fruits and vegetables, and even fresh meat and poultry packaged in high oxygen environments), any of which could theoretically be subject to temperature abuse sufficient to promote spoilage or the growth of pathogens (if any) without a noticeable change in product color. For most perishable foods, including fresh meat, consumers have a long history of relying upon open code dates along with odor and other signs that the product may not be suitable for consumption (e.g., slime).

- **European policy is not relevant to the U.S. GRAS standard.** In an attempt to question the GRAS status of CO, Kalsec points to an EU policy decision in which a Committee of the European Parliament

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inhibitory effect does not render a packaging system or mixture of gases unsafe. For instance, Nissen's finding that *Yersinia enterocolitica* grew more vigorously in Chub and high O_2 packages than a high CO_2/low CO mixture certainly does not call into question the safety of either of those systems.

voted not to authorize the use of CO in fresh meat packaging. The legal status of a material in the European Union or any other political system has no bearing on a GRAS assessment in the United States. There are numerous instances in which substances and technologies are deemed safe in the United States but not Europe (and vice-versa), as evidenced by the longstanding disputes over beef hormones, regulation of modern biotechnology, and the so-called "precautionary principle." What matters from the perspective of the "common knowledge" element of a GRAS determination is not the policy of any particular government; the issue is whether qualified experts consider the substance to be "safe" for its intended conditions of use. Governments may reject an additive for reasons other than safety, or they may choose a more conservative position than the scientific evidence would suggest is necessary. 10/ In Europe, for example, a food additive may be rejected if a technological need for the additive is not demonstrated.

- **The European scientific assessment supports GRAS status.** In contrast to the political assessments of CO, a 2001 opinion of the Scientific Committee on Food (SCF) reflects that Committee's determination that CO is safe under its intended conditions of use in fresh meat packaging. 11/ The Committee specifically examined the

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10/ The vote by the European Parliament on CO is obviously political and not scientific in nature. In addition, the treatment of CO by the European Commission, Health & Consumer Protection Directorate-General appears to have been driven by concerns other than safety—namely, the issue of whether CO misleads the consumer with respect to product freshness. Letter from Robert J. Coleman, European Commission, to Mrs. Caroline F. Jackson, European Parliament (Attachment 4). The discussion of this issue by the Commission necessarily reflects a European perspective and is no more binding on FDA or USDA than EU requirements addressing the labeling of products of modern biotechnology, quantitative ingredient labeling, or similar matters. With respect to safety, the Commission stated that CO "may" present a health hazard if packaged meat is not handled appropriately, "as it may mask spoilage." Any meat may present a hazard if it is not handled in accordance with its intended conditions of use; as for spoilage, the data show that the appropriate use of CO will not mask signs of spoilage such as odor, gas formation, and slime formation.

11/ Opinion of the Scientific Committee on Food on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat, SCF/CS/ADD/MSAd/204 Final (18 Dec. 2001)(Attachment 5).

safety of CO (0.3%-0.5%) used in combination with carbon dioxide (CO_2)(60%-70%) and nitrogen (N_2)(30%-40%). The Committee concluded that "there is no health concern associated with the use of 0.3%-0.5% CO in a gas mixture of carbon dioxide and nitrogen as a modified atmosphere packaging gas for fresh meat provided temperature during the storage and transport does not exceed 4°C." 12/ The Committee's emphasis on the need for temperature control is appropriate and important for any fresh meat product. With respect to storage under inappropriate conditions, the Committee concluded that CO "may mask visual evidence of spoilage," which presumably refers to the color stabilizing effect of CO. "Spoilage" is a subjective term that is frequently measured in different ways (e.g., odor spoilage, visual spoilage, microbial spoilage, etc.).

- **The history of safe use of CO MAP systems in Norway and the United States supports safety and suitability.** The use of CO in MAP systems for fresh meat is not new or experimental. Such systems were used in Norway from the mid-eighties until 2004, when the EU policy on CO forced Norway to discontinue its use. As the SCF noted in its scientific opinion, the use of CO in Norway was substantial (CO was used in approximately 50-60% of retail meat and up to 85% ground beef packaging) and "no outbreaks or a higher frequency of sporadic cases of food-borne diseases" had been linked to these products during that time. 13/ In this country, CO has been used since 2002 in at least 100 million fresh meat packages. In the experience of Precept Foods, consumer acceptance of meat products packaged in CO-containing environments has been excellent, with no evidence of increased complaints due to spoilage or other issues.

- **Use of CO expands the use of low oxygen packaging and offers real consumer benefits.** Contrary to Kalsec's assertions, CO does afford important consumer benefits that are not feasible with other packaging systems. Most significantly, CO-containing MAP systems combine the benefits of low oxygen packaging systems (which offer quality and other advantages) with the color-stabilizing benefits of

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12/ *Id.* at 7.

13/ *Id.* at 5.

high oxygen systems, but without the quality disadvantages posed by high oxygen. This is, of course, precisely the basis for Kalsec's concern—Kalsec sells antioxidants that help to prevent the detrimental effects of high oxygen systems. Use of CO allows the meat industry to deliver high quality meat products with efficiency and with the aid of modern technology.

- **Labeling of CO is not required.** As our January 23, 2006 letter explained, the use of CO in a modified atmosphere does not trigger any labeling requirement. The presence of CO is not material information because the intended conditions of use ensure that consumers have important product information: the label includes a use-or-freeze by date that conveys a validated shelf life; safe handling instructions advise consumers on proper preparation of the raw meat; and signs of spoilage (e.g., odor, slime formation, bulging packages) will be evident in the unlikely event of spoilage during the product's shelf life. 14/ Further, like other packaging gases used with fresh meat and poultry, CO does not function as an ingredient and has no lasting technical or functional effect. The CO is rapidly removed from the atmosphere and the product once the package is opened (with only residual levels remaining) and has no effect on meat products as consumed. Thus, as is the case with other packaging gases (e.g., CO_2, O_2), there is no basis for labeling CO. Indeed, there is no reasonable basis for distinguishing CO from other packaging gases—for instance, high O_2 environments are also used to stabilize color in meat products as packaged, but FSIS has never required labeling of added oxygen.

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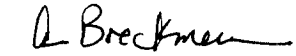
14/ Significantly, since the agencies first decided to permit CO-containing packaging systems several years ago, well over 100 million packages have been successfully sold in this format in the Unites States. The U.S. experience adds to that of Norway and confirms that these systems can and are being used appropriately.

We appreciate FDA's consideration of these additional comments. Please do not hesitate to contact us if there are any questions or if additional information would be useful.

Sincerely,



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Enclosures

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