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5100 Paint Branch Parkway
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Re: Citizen Petition Requesting FDA to Enforce Ban on Carbon Monoxide in Case-Ready Fresh Meat Packaging; Docket No. 2005p-0459

Dear Dr. Tarantino:

This letter responds to comments by Precept Foods, LLC ("Precept") to the docket for the citizen petition filed by Kalsec, Inc. ("Kalsec"), which seeks a ban on the use of carbon monoxide in fresh meat packaging. The comments filed by Precept, while consuming nearly 20 typewritten pages, contribute no material legal or factual information, and constitute a calculated effort to distract attention from the legal standards that establish FDA's obligation to enforce a ban on carbon monoxide immediately.

The Precept comments are deficient in four key respects:

- Precept mischaracterizes the governing statute and regulatory precedents, and mischaracterizes the nitrite precedent;
- Precept mischaracterizes FDA regulations prohibiting carbon monoxide in fresh meat and ignores the statutory distinction between food additives and GRAS (Generally Recognized as Safe) substances;
- Precept's assertion that its intended use of carbon monoxide is GRAS ignores the "general recognition" requirement; and
- The use of carbon monoxide in fresh meat packaging must be declared in labeling.

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The Kalsec petition urges FDA to take immediate action to enforce a ban on carbon monoxide in fresh meat packaging, including by terminating the agency's unlawful acceptance of the Generally Recognized As Safe ("GRAS") notifications submitted by Pactiv Corp. and Precept Foods, Inc. (GRAS Notice Nos. GRN 000083 and 000143). As detailed in the Kalsec petition, the use of carbon monoxide gas in fresh meat packaging produces an artificially intense, persistent red color in meat that can simulate the look of fresh meat and mask the natural signs of aging and spoilage that consumers depend upon in making safe food choices. The Kalsec petition raises concerns that, particularly in the absence of distinctive labeling disclosing the use of carbon monoxide in fresh meats, such use gambles with consumer confidence in the safety and integrity of the case ready meat supply, generally, since consumer cannot tell whether carbon monoxide has been added to their meat.[1]

At set forth in the Kalsec petition, FDA is obligated to enforce the ban on carbon monoxide in fresh meat under the Federal Food, Drug and Cosmetic Act ("FDCA") and current FDA regulations, as a matter of law.

I. Precept Mischaracterizes the Governing Statute and Regulatory Precedents and Mischaracterizes the Nitrite Precedent

Precept's comments urge FDA to ignore the Kalsec petition, mischaracterizing its legal rationale in arguing that the petition relies solely and improperly on FDA's determination concerning the use of nitrite in bacon. While complaining that the Kalsec petition provided an incomplete description of the nitrite record, the Precept submission fails to reference, much less address, the relevant law, regulations, and substantial body of regulatory precedent that establish the color additive status of carbon monoxide use in fresh meat, and thus subject carbon monoxide use in fresh meat to the requirements of section 721 of the FDCA.

The starting point for determining whether carbon monoxide constitutes a prohibited "color additive," is the statute. The plain language of FDCA section 201(t)(1) defines "color additives" to encompass not only added dyes and pigments, but also colorless substances that impart color through chemical reactions that generate color after addition. As detailed in the Kalsec petition, FDA repeatedly has determined that FDCA section 721 applies to colorless substances that "impart color" through color generating chemical reactions occurring after the substance is added. Precept's argument ignores not only the statute, but also the further support for the Kalsec petition provided by the FDA color additive determinations concerning

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[1] Kalsec participates in the case ready meat business with one if its natural spice extracts. Kalsec has a substantial interest in ensuring that consumer confidence in the safety and integrity of the meat supply is preserved.

dihydroxyacetone, lead acetate, bismuth citrate, dried algae meal, tagetes/Aztec marigold, astaxanthin, and haematococcus algae,[2] in addition to nitrite.

The FDA record concerning the use of nitrite as a curing agent in bacon provides no support for Precept's argument opposing the regulation of carbon monoxide as a color additive. As the Kalsec petition makes clear, a careful reading of the particularly contentious record in the nitrite case shows that, to the extent the 1980 FDA determination concerning bacon-nitrite arguably is relevant, the record establishes that colorless substances participating in chemical reactions with myoglobin that produce visible color changes in meat must be considered under the "color imparting" standard of the color additive definition, just as FDA regulates colorless substances reacting with other components of the articles to which they are applied.[3]

The Kalsec petition cites the bacon-nitrite precedent, along with numerous others, to make a simple point: it is well settled that the color additive requirements set forth in section 721 of the FDCA apply not only to added color pigments, but also to substances that participate in chemical reactions that generate color after they are added. The Kalsec petition makes clear that FDA ultimately concluded that nitrite should not be regulated as a color additive under section 721. At no time, however, did FDA reverse its position that "color additives" include colorless substances that impart color through chemical reactions, or otherwise determine that substances participating in color-imparting reactions involving myoglobin in meat were categorically excluded from the definition of color additives.

To the contrary, even in reversing its tentative conclusion that nitrites constituted "color additives," FDA was careful to validate the relevance of its earlier focus on the chemical reactions involving myoglobin. Nothing in FDA's final determination suggests that considering chemical reactions with myoglobin is irrelevant in determining whether a substance must be regulated as a color additive. Rather, FDA's final determination concluded that its earlier analysis had focused too narrowly on the color-imparting chemical reaction, and had not given sufficient weight to key historical and regulatory distinctions concerning nitrite use as a curing agent which authorized FDA to regulate nitrites as "color fixatives"[4] rather than "color additives." In articulating the basis for its final determination, FDA took care in justifying the color additive analysis that led to its tentative conclusion, indicating that, color imparting reactions involving myoglobin could provide a "plausible basis" for concluding that a substance

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[2] *See* 21 C.F.R. §§ 73.2150, 73.2396, 73.2110, 73.275, 73.295, 73.35 and 73.185.

[3] *See* fn. 2, *supra*, and accompanying text.

[4] See 21 C.F.R. 170.3(o)(4) (defining "colors and coloring adjuncts" to mean "substances used to impart, preserve, or enhance the color or shading of a food, including color stabilizers, color fixatives, color-retention agents, etc.").

"imparts" color and constitutes a "color additive" subject to the requirements of FDCA section 721.[5]

Moreover, contrary to Precept's argument, providing a more detailed account of FDA's final determination on nitrite use in bacon in 1980 not only lends no support to Precept's claim, but further bolsters the Kalsec petition. While recognizing that nitrite curing agents participate in chemical reactions with myoglobin, FDA ultimately determined that these constituted color-preserving reactions that were associated with the curing process and thus qualified as "color fixatives" rather than "color additives." In this regard, FDA's determination concerning nitrite use in curing bacon was founded on several key scientific, historical, and regulatory distinctions which have no application to the use of carbon monoxide in fresh meat.

- FDA observed that the effect of nitrites is to maintain the myoglobin in a stable form that is red in color, and that the addition of more nitrites did not increase the intensity of the red color.[6] By contrast, a greater concentration of carbon monoxide does produce a more intense red color, and cannot be said to merely "maintain" the myoglobin in a stable form. As noted in the study by Sørheim, *et al.*, referenced in Precept's comments, the color of meat stored in a modified atmosphere containing 2% carbon monoxide was characterized as "too artificial" by a sensory panel, while 0.4% carbon monoxide "seems sufficient to produce a stable, attractive, bright red colour of meat."[7]

- FDA discussed legislative history indicating that the color additive amendments were intended to regulate substances that make color changes in food that are visible to the

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[5] *See* 45 Fed. Reg. 77043, 77045 (November 21, 1980) (FDA explained that, "[b]y focusing almost exclusively on the details of the chemical reaction that occurs when nitrites are added to bacon, the Public Citizen petition appears to provide a plausible basis for concluding that nitrites 'impart' color, and FDA tentatively adopted Public Citizen's position in its response to the citizen petition." Additionally, while FDA ultimately concluded that its tentative conclusion that nitrites "impart" color "focused too narrowly on the chemical reactions that occur when nitrites are added to bacon and other red meats and failed to give adequate weight to the practical meaning of the 'color additive' definition and FDA's past interpretation of it," the agency made no suggestion that the agency intended to establish a more general exemption from FDCA section 721 for other meat additives participating in color generating chemical reactions with myoglobin in meat.).

[6] 45 Fed. Reg. at 77045.

[7] Sørheim, O., *et al.*, "The Storage Life of Beef and Pork Packaged in an Atmosphere with Low Carbon Monoxide and High Carbon Dioxide," 52 Meat Science 157-164 (1999), at 162-63 (Attachment 1).

naked eye. The agency observed that the color of nitrite-cured bacon was not readily distinguishable from the color of uncured pork belly at or shortly after slaughter.[8] The same cannot be said of carbon monoxide, however, which imparts a bright red color to naturally purple freshly slaughtered meat.[9]

- Nitrites produce a visible change in color of meat only after cooking. FDA concluded that the color additive definition did not require the agency to account for this effect, finding that Congress did not intend substances like sugar that change color from ordinary cooking to be regulated as color additives. Carbon monoxide, however, produces color change in uncooked meat.

- In continuing to treat nitrites as "color fixing" rather than "color imparting" substances, FDA recognized nitrites' long history of safe use to cure and preserve meats. While "color fixing" is a property common to "preservatives," neither carbon monoxide (nor carboxymyoglobin) has a history of use as preservatives and they do not function to cure meat or otherwise enhance the safety of fresh meat products.

- FDA's decision to continue regulating nitrites as preservative and color fixative food additives was consistent with the historical policy of USDA and FDA to distinguish "coloring agents" (such as coal tar dyes) from curing agents, whose purposes include the "fixation" of color.[10] FDA acknowledged that no new facts had surfaced to justify a change in the agency's longstanding classification. By contrast, the only prior regulatory classification of carbon monoxide in fresh meats is FDA's ban on its use as part of combustion products gas.

Thus, FDA's ultimate determination to retain its historical classification of nitrites as food additives that function as "color fixatives" and preservatives in cured meats was based on factors unique to nitrites, and provides no basis for regulating carbon monoxide in fresh meats as anything other than a color additive. Further, the subsequent judicial decision upholding FDA's determination, largely on grounds of administrative law, not only provides no support for applying that determination to carbon monoxide, but also highlights as the basis for that determination factors unique to nitrites and distinct from the use of carbon monoxide in fresh

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[8] 45 Fed. Reg. at 77045, 77046.

[9] For example, if freshly slaughtered meat is placed in an oxygen-free modified atmosphere like Precept's but without the carbon monoxide (carbon dioxide and nitrogen only), the meat will appear dark purple, due to the presence of the natural pigment deoxymyoglobin. However, when 0.4% carbon dioxide is added, the meat will appear bright red, due to the creation of the new pigment carboxymyoglobin.

[10] 45 Fed. Reg. 77043, 77046 (November 21, 1980).

meat.[11] The important distinctions between nitrites and carbon monoxide, along with the statutory definition of "color additive" and FDA's relevant regulatory precedents, direct the conclusion that carbon monoxide is a color additive because it imparts color to fresh meat through chemical reaction.

II. Precept Mischaracterizes FDA Regulations Prohibiting Carbon Monoxide in Fresh Meat and Ignores the Statutory Distinction Between Food Additives and GRAS Substances

In arguing that the use of carbon monoxide is not prohibited by FDA's food additive regulation for combustion products gas, Precept ignores relevant science and governing language, and fails to consider the overall regulatory framework at issue.

Precept's discussion of the components of combustion products gas disregards the key scientific facts demonstrating that the prohibition of this additive for use in fresh meats is attributable to the color-imparting effect of carbon monoxide in the gas mixture. In asserting that nitrogen and carbon dioxide have been separately affirmed as GRAS for use in foods generally, Precept glosses over clear distinctions between these gases. Nitrogen and carbon dioxide are inert and do not react appreciably with fresh meat, while carbon monoxide is reactive and forms a new pigment, carboxymyoglobin, in the meat.

It is this unique, color-imparting reaction of carbon monoxide with fresh meat that justifies the limited prohibition from the otherwise broad scope of use of the additive in the packaging of all other food and beverage products, including other meat and poultry products.[12] The prohibition is consistent with the framework for FDA's regulation of color additives and the agency's authority to promulgate food additive specifications that complement the prohibited uses under the color additive provisions of the FDCA.

Precept's suggestion that FDA prohibits substances for use in food only through a regulation codified in 21 C.F.R. Part 189 ignores not only the interplay between the food additive and color additive regulatory frameworks, but also the plain language in 21 C.F.R. § 189.1(b) stating that this part "includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully

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[11] For example, the court pointed to Congressional intent to regulate as color additives substances that impart new colors apparent to the naked eye and observed that nitrites do not produce visible color change prior to cooking, highlighted that the coloring effect of nitrites was incidental to its purpose in preventing botulism, and that the use of nitrites is justified as a public health measure. *Public Citizen v. Hayes*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,161 (D.D.C. 1982).

[12] Notably, the food additive regulation does not carve out all USDA-regulated meat and poultry products.

be used in human food." Thus, Precept mischaracterizes Part 189 entirely and provides no legal support for its argument that the prohibition on carbon monoxide in fresh meat is an exception to the scope of coverage of the combustion products gas food additive regulation. An examination of that regulation makes clear, as described in Kalsec's petition, that the rule encompasses and regulates the conditions of safe use of carbon monoxide to remove or displace oxygen in the packaging of food and beverage products, and that one such condition is the prohibition of the substance for use in fresh meat packaging.

Because carbon monoxide is affirmatively prohibited by regulation for use in fresh meats, it is not merely an "unapproved food additive" that can become GRAS over time. In suggesting this possibility, Precept mischaracterizes the statutory and regulatory framework that allows the repeal of regulatory prohibitions only through notice and comment rulemaking. While with the passage of time, through advancing science and accumulated experience with safe use, certain conditions of use of approved food additive substances may become generally recognized as safe, food additive specifications establishing limits on the conditions of use cannot be ignored or amended through the GRAS premarket notification procedure.

First, this is a matter of legal procedure which is governed by the Administrative Procedure Act ("APA"), and it is an axiomatic principle of administrative law that an agency's codified rules may not be amended outside of notice-and-comment rulemaking.[13] Second, FDA policy in this arena is consistent with APA requirements, for, as discussed in the vitamin D rulemaking to which Precept cites, expansion of the use of even a GRAS substance beyond limitations established by regulation requires rulemaking in the form of either a food additive regulation or an amendment of the GRAS regulation,[14] and cannot be accomplished through a GRAS notification.[15] Third, there is no statutory requirement that GRAS notifications be submitted to FDA, and current notification procedures constitute practices aligning with an FDA proposed rule which, even if made final, would remain voluntary procedures.

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[13] *See, e.g., Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) ("new rules that work substantive changes in prior regulations are subject to the APA's procedures" at 5 U.S.C. § 553 requiring notice-and-comment rulemaking); *U.S. Telecom. Assn. v. FCC*, 400 F.3d 29, 38 (D.C.Cir. 2005) (an agency's action which "substantively changes a preexisting legislative rule ... can be valid only if it satisfies the notice-and-comment requirements of the APA").

[14] 70 Fed. Reg. 69435, 69436 (November 16, 2005).

[15] *See* Letter from Alan M. Rulis, Ph.D., Director, Office of Premarket Approval, CFSAN, to Clausen Ely, Jr. (May 26, 1999) ("Agency Response Letter to GRAS Notice No. GRN 000014"), available at http://www.cfsan.fda.gov/~rdb/opa-g014.html (refusing to accept GRAS notification for use of hydrogen peroxide beyond limits established in GRAS regulation because such change requires rulemaking either to amend the GRAS regulation or promulgate a food additive regulation).

Precept's argument that FDA regulations limiting the conditions of use for a food additive can be amended through a voluntary GRAS notification is therefore unfounded and contrary to law. Moreover, the two GRAS precedents upon which Precept purports to rely provide no support for its argument, for in neither case did FDA allow, through acceptance of a GRAS notification, new conditions of use that had previously been prohibited by regulation.[16]

In sum, the Precept arguments have no bearing on the regulatory status of carbon monoxide in food packaging. FDA's food additive regulation at 21 C.F.R. § 170.350 expressly forbids the use of carbon monoxide in fresh meat products. This prohibition cannot be ignored or overcome through FDA's informal, voluntary GRAS notification procedures.

III. Precept's Assertion that its Intended Use of Carbon Monoxide is GRAS Ignores the "General Recognition" Requirement

Precept's assertion that the use of carbon monoxide is GRAS again fails to consider the relevant statutory language – that such substances must be "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use."[17] FDA explains 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."[18] Precept nowhere acknowledges that the use of carbon monoxide in modified atmosphere packaging for fresh meat has been banned in Europe, after the European Commission's Scientific Committee on Food evaluated the evidence and concluded that the presence of carbon monoxide could cause color change that would mask visual evidence of microbial spoilage.[19] The European Union has also banned carbon monoxide in fresh fish on the same grounds, as have most other countries that have addressed the issue, including Canada, Japan, and Singapore.[20] Given this well-documented and ongoing scientific

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[16] GRAS Notice No. GRN 000104 for sucrose acetate isobutyrate ("SAIB") expanded the use of the additive previously authorized for use in non-alcoholic beverages to include use in alcoholic beverages, which use had not been addressed in the existing food additive regulation. GRAS Notice No. GRN 000091 addressed mycoprotein, a substance for which FDA had not previously promulgated a food additive.

[17] 21 U.S.C. § 321(s).

[18] 62 Fed. Reg. 18938, 18942 (April 17, 1997) (GRAS Notification Proposed Rule).

[19] Opinion of the Scientific Committee on Food on the Use of Carbon Monoxide as Component of Packaging Gases in Modified Atmosphere Packaging for Fresh Meat, SCF/CS/ADD/MSAd/04 (December 18, 2001) (Attachment 2).

[20] *See* discussion at p. 22 of Kalsec's citizen petition and attachments thereto.

controversy, the use of carbon monoxide in fresh meat packaging cannot be deemed "generally recognized as safe."

Precept's lengthy defense of reduced oxygen packaging systems in general is an irrelevant diversion. Kalsec's petition does not challenge reduced oxygen packaging systems for meat as a class; it challenges only carbon monoxide-containing systems, for which there is no consensus as to safety. Precept's discussion of the likelihood of *C. botulinum* and *L. monocytogenes* contamination are similarly inapt given the documented controversy surrounding the use of carbon monoxide in fresh meat packaging. Further, while asserting that Kalsec exaggerates the potential for temperature abuse in the distribution chain and arguing that safe handling instructions and other controls guard against this risk, Precept fails to address the results of peer-reviewed scientific studies cited in Kalsec's petition that indicate temperature control in the distribution chain is inadequate, and the recognition of this inadequacy as a grounds for the European ban on carbon monoxide in fresh meat packaging.[21]

Precept's comments acknowledge that temperature abuse and even spoilage will not be evident by the color of meat packaged in its carbon monoxide-containing modified atmosphere, and therefore Precept admonishes that consumers are "better served" by relying on "use or freeze by" dates and signs of temperature abuse other than color. In this regard, Precept attempts to retrain millions of consumers away from their accustomed cue – color – as to the freshness of meat, as documented in the numerous scientific journals and industry publications cited in Kalsec's petition. Such efforts cannot translate into the requisite demonstration of safety under actual conditions of use, particularly where Precept provides no evidence of consumer behavior to support its recommendations.

In its discussion of indicators of spoilage in a carbon monoxide-containing packaging atmosphere, Precept attempts to discredit the study commissioned by Kalsec and attached to its petition demonstrating that microbial spoilage is not apparent through color change in meat packaged with carbon monoxide. Again, these unfounded criticisms are a diversion from the key issues, for Kalsec's study served only to bring to FDA's attention factual information that appears to corroborate the concerns documented in the scientific literature that color imparted to meat by carbon monoxide has the potential to mask spoilage.

Finally, Precept's assertion that its packaging system offers meaningful consumer benefits is irrelevant to a determination of general recognition of safety, and appears to be an attempt to portray the use of carbon monoxide as a magnanimous gesture by Precept. Notably,

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[21] Additionally, in the January 22, 2006, broadcast of NBC's "Dateline," a feature on supermarket safety also documented significant incidence of temperature abuse at retail. *See* "How Safe is Your Grocery Store," at http://msnbc.msn.com/id/10976595/.

there is evidence that the coloring effects of carbon monoxide have the potential to reduce significant commercial losses associated with the discounting of meat that has discolored.[22]

It is notable that the supposed benefits attributed to Precept's system are neither unique to Precept's products nor attributable to the presence of carbon monoxide in the packaging system. All case ready products share the benefits of centralized processing from a smaller number of inspected production sites. Further, the use of a single date code throughout the distribution system is not "made possible by CO" but could be devised for other packaging systems as well. Such a code provides little value, however, where consumers' well-documented primary indicator of freshness – color – has been manipulated.

IV. Use of Carbon Monoxide in Fresh Meat Packaging Must be Declared in Labeling

Precept argues that the use of a modified atmosphere is not a material fact requiring labeling, but Kalsec has made no such contention. Rather, the material fact that must be identified on the food label is the presence and purpose of carbon monoxide in the modified atmosphere.[23] Sections 201(n) and 403(a) of the FDCA require this declaration because the use of carbon monoxide is material in light of the representation that the meat is unprocessed and untreated and that its color is a reliable indicator of its freshness, and because of the serious food safety risks attendant to such representation. Further, carbon monoxide in fresh meat packaging functions as a color additive, which must be declared in labeling.[24]

Precept's comments acknowledge that the color of meat packaged with carbon monoxide fails to provide evidence of spoilage or temperature abuse, and Precept does not dispute that color is the primary indicator of freshness upon which consumers rely. Accordingly, Precept provides no basis for excluding carbon monoxide from the disclosure requirements mandated by the FDCA in this context.

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[22] *See, e.g.*, J. Brad Morgan, "Extending Shelf-Life of Beef Cuts Utilizing Low Level Carbon Monoxide in Modified Atmosphere Packaging Systems," Project Summary Prepared on behalf of the Cattlemen's Beef Board by the National Cattlemen's Beef Association Center for Research & Knowledge Management, Funded by America's Beef Producers, July 2003 (Attachment 3), available at http://www.beef.org/reseresearchprojectsummaries.aspx, at 4 ("U.S. retailers fail to capture at least one billion dollars of revenue annually from fresh beef sales, due to product discoloration. The findings of this study suggest that CO MAP could contribute to longer shelf life for T-bone steaks, sirloin steaks and ground beef patties.").

[23] Notably, the use of nitrites in meats, to which Precept compares carbon monoxide, must be identified on the food label, and their function is well understood by consumers due to their long history of use.

[24] 21 U.S.C. § 403(k).

Kalsec would be happy to provide any additional information regarding its citizen petition and these comments, or to respond to any questions regarding this matter.

Respectfully submitted,

Don Berdahl/sk

Don Berdahl
Vice President/Lab Director
Kalsec, Inc.

Attachments

cc: FDA Division of Dockets Management

Dr. Andrew C. von Eschenbach, Acting Commissioner of Food and Drugs, FDA
Dr. Barbara J. Masters, Administrator, FSIS, USDA
Sheldon Bradshaw, Chief Counsel, FDA
Dr. Robert E. Brackett, Director, CFSAN, FDA
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Scott Gottlieb, Deputy Commissioner for Policy, FDA
Michael Landa, Deputy Director for Regulatory Affairs, CFSAN, FDA
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