

**DOCKET NO. FDA-2009-D-0542**

**BEFORE  
THE UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**COMMENTS OF THE  
AMERICAN HERBAL PRODUCTS ASSOCIATION  
AND THE  
INTERNATIONAL ALOE SCIENCE COUNCIL**

**ON THE  
FOOD AND DRUG ADMINISTRATION'S  
DRAFT GUIDANCE FOR INDUSTRY TITLED**

**“FACTORS THAT DISTINGUISH LIQUID DIETARY SUPPLEMENTS FROM  
BEVERAGES, CONSIDERATIONS REGARDING NOVEL INGREDIENTS, AND  
LABELING FOR BEVERAGES AND OTHER CONVENTIONAL FOODS”**

**February 2, 2010**

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods and dietary supplements.

The International Aloe Science Council (IASC) is a non-profit trade organization for the *Aloe vera* industry world-wide. IASC includes *Aloe vera* growers, processors, finished goods manufacturers, marketing companies, and others, and promotes *Aloe vera* for its many uses, including as an ingredient in foods and in dietary supplements. IASC serves as a liaison and source of information for research, development and promotion of *Aloe vera* and associated products.

## **Background**

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines a dietary supplement to mean, among other things, a product that “is intended for ingestion ... in a liquid form ... in daily quantities measured in drops or similar small units of measure,” or “if not intended for ingestion in such a form, is not represented for use as a conventional food or as a sole item of a meal or the diet.”<sup>1</sup> Thus, dietary supplements may be sold in a liquid form in larger quantities of measure under certain conditions.

The Food and Drug Administration (FDA or the agency) announced on December 4, 2009 the availability of draft guidance for industry, “Factors that distinguish liquid dietary supplements from beverages, considerations regarding novel ingredients, and labeling for beverages and other conventional foods” (the draft guidance or the draft). The agency stated that the draft guidance “describes factors that can be used to identify liquid products that are excluded from being dietary supplements because they are represented as conventional foods” and “reminds manufacturers and distributors of beverages and other conventional foods, particularly those that contain novel ingredients, about the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding ingredients and labeling.”

The issuance of this draft guidance is not the first time that FDA has addressed the issue of the regulatory boundaries between dietary supplements and conventional foods. In developing regulations for labeling of dietary supplements in 1995 and 1997, the agency addressed and provided detailed analyses of how these two product categories are differentiated.

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<sup>1</sup> 21 U.S.C. §§ 321 (ff)(2)(A)(i), 350 (c)(1)(B), and 350 (c)(2).

AHPA and IASC are therefore providing comments on the draft guidance with reference to prior agency statements on supplement-food boundaries.

**Prior FDA communications on differentiating between dietary supplements and conventional foods are relevant to products in liquid form and to the draft guidance**

The agency issued a proposed rule in December 1995<sup>2</sup> and a final rule in September 1997<sup>3</sup> to amend federal food labeling regulations to establish requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling in response to the Dietary Supplement Health and Education Act (DSHEA). In the preambles to these rulemaking publications, FDA included numerous statements relevant to whether a product is a conventional food or a dietary supplement.

For example, in the 1995 proposed rule, the agency provided the following preamble comments:

- "... the agency points out that it is proposing to change the language in § 101.12(b), Table 2, to read 'Dietary supplements' instead of 'Dietary supplements not in conventional food form' in response to the DSHEA. ... The DSHEA ... evidences an intent, for labeling purposes, to treat all dietary supplements in a similar manner. In particular, section 7 of the DSHEA addresses dietary supplement labeling and does not distinguish between dietary supplements that are not in conventional food form and those that are."<sup>4</sup>
- "... to signal to consumers that nutrition labeling on dietary supplements differs in several significant respects from that on conventional foods, FDA is proposing in §101.36(e)(1) that the title for the nutrition information on packages of dietary supplements be "Supplement Facts." The agency tentatively concludes that the title "Supplement Facts" and the proposed format structure are sufficiently similar to the title "Nutrition Facts" and the format requirements used in nutrition labeling of conventional foods for the consumer to immediately recognize that the information in the two boxes is related. However, by the use of a different name, the consumer can be taught to recognize the basic structural differences in nutrition information on dietary supplements will have the quantitative amounts by weight located in a separate column; may include source ingredients; and may not have a "% Daily Value" column if no dietary ingredients having RDI's or DRV's are present in the product."<sup>5</sup>

Equally relevant commentary was included in the preamble to the 1997 final rule, including:

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<sup>2</sup> 60 FR 67194, December 28, 1995.

<sup>3</sup> 62 FR 49825, September 23, 1997.

<sup>4</sup> 60 FR 67194 at 67196.

- "... the decision whether a product is sold as a dietary supplement is made by the manufacturer."<sup>6</sup>
- "... dietary supplements may be similar to conventional foods in composition and form. Whether a product is a dietary supplement or a conventional food, however, will depend on how it is represented. ... For example, the manufacturer of a product that is in the form of a tablet or capsule that has nutritive value or a powdered herbal product with no nutritive value may choose to market the product as a conventional food that bears nutrition labeling in accordance with Sec. 101.9."<sup>7</sup>

The agency provided additional relevant commentary in the preamble to a separate final rule published in September 1997 addressing nutrient content claims, health claims, and statements of nutritional support for dietary supplements,<sup>8</sup> including:

- "The distinction between dietary supplements and conventional foods becomes more apparent when the act is read carefully. The DSHEA added section 201(ff)(2) which provides that a 'dietary supplement' is a product that is not represented for use as a conventional food. It also struck the provision that excluded products that simulate conventional foods from the coverage of section 411 of the act (see section 3(c)(2) of the DSHEA). Thus, under the act, as amended by the DSHEA, a dietary supplement may be 'in conventional food form.' In other words, a dietary supplement may be a product with physical attributes (e.g., product size, shape, taste, packaging) that are essentially the same as a conventional food, so long as it is not represented for use as a conventional food."<sup>9</sup>
- "... whether a product is a dietary supplement or a conventional food will depend on how it is labeled."<sup>10</sup>
- "While the term 'dietary supplement' in the statement of identity is a necessary condition for a product to be represented as a dietary supplement, it may not be enough to establish that the food is appropriately regulated as one. If the food is represented as a dietary supplement and is only intended to increase the dietary intake of specific substances (e.g., vitamins), then the product would likely be subject to regulation as a dietary supplement (section 201(ff)(1) of the act). It would not be subject to regulation as a dietary supplement, however, if it bears a statement that associates it with a conventional food. For example, a product in bar form that is labeled as a dietary supplement but that also bears

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<sup>5</sup> Id. at 67205.

<sup>6</sup> 62 FR 49825 at 49837.

<sup>7</sup> Id.

<sup>8</sup> 62 FR 49859, September 23, 1997.

<sup>9</sup> Id. at 49862.

<sup>10</sup> Id.

label statements that represent it as a snack food or as a substitute for a candy bar would be subject to regulation as a conventional food. Similarly, a breakfast cereal-type product could characterize itself as a dietary supplement if it did not represent itself as a breakfast food or use the term 'cereal' as a statement of identity. Either of the latter two scenarios would represent the product as a conventional food.”<sup>11</sup>

AHPA and IASC read these statements by FDA as the agency's recognition that the Congress intended, and in fact did establish that a dietary supplement could be marketed in a conventional food form so long as the supplement is not represented for use as a conventional food. In emphasizing that differentiation between dietary supplements and conventional foods depends on how a product is labeled, the agency made no attempt to communicate that any particular conventional food form should not be available for dietary supplement products, and in fact provided examples of various "conventional foods" that could be lawfully marketed as dietary supplements with appropriate labels and labeling. In addition, the regulations long established by FDA allow dietary supplements to be labeled in certain manners that are also associated with conventional foods, such that, for example, dietary supplements (including dietary supplements in conventional food form) may make nutrient content claims.

It is also apparent that the agency is aware that the applicable statutory definition of dietary supplements restricts such products from representation for use as conventional foods, but does not restrict them from being in conventional food form. Any product labeled as a dietary supplement, regardless of form, and providing conditions of use principally intended to supplement the diet should be regulated as a dietary supplement so long as it is not also represented to be used as a conventional food or as a sole item of a meal or the diet.

AHPA and IASC are concerned that FDA's draft guidance fails to note and take into account these prior agency statements regarding dietary supplements in conventional food form, and request that any final guidance be revised as needed to make all of the points previously communicated by the agency.

**Packaging and serving size should not be factors that are indicative of whether a liquid supplement product is represented as a conventional food**

FFDCA allows dietary supplements to be in conventional food form, so long as they are not "represented for use as a conventional food," and the agency has recognized that they may be similar to conventional foods. Packaging and serving size are necessary components of the form a food takes.

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<sup>11</sup> Id.

FDA overreaches when it suggests that packaging or serving size may be factors (and potentially the only factor) that are indicative of whether a liquid supplement product is represented as a conventional food. The serving sizes established by FDA for conventional foods are not thereby reserved for conventional foods only. That is nowhere stated in any food labeling regulation. Similarly, there is no regulation that implies that any form of packaging is reserved to conventional foods and not available for dietary supplements. Simply stated, neither packaging nor serving size “represents” the form of a food. The first is required to carry and preserve the food for the consumer, and the second is required by law to be stated as part of the nutrition information for both dietary supplements and conventional foods.

**The draft guidance should consistently identify factors as indicators of product class rather than as absolute determinants**

The draft guidance states that the agency “considers a liquid product’s name, packaging, serving size, and recommended conditions of use, as well as other representations about the product, to be important determinants of whether the product is represented as a conventional food and may not be marketed as a dietary supplement.” Except as stated above with respect to serving size and packaging, AHPA and IASC believe that this statement correctly identifies factors as issues that may be considered in determining whether a liquid product is marketed as a conventional food or as a dietary supplement, but do not believe that any single one of these factors, in and of itself, is necessarily determinant of the product class.

The draft guidance, however, is not consistent in identifying each of these factors as only possible indicators of product class. For example, the draft guidance states that “the name of a product can represent the product as a conventional food” (emphasis added), and AHPA and IASC agree that the name of a product may be an indicator as to whether a liquid product is a conventional food or a dietary supplement.

But the draft guidance also states, “Liquid products that suggest through their serving size, packaging, or recommended daily intake that they are intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the U.S., are represented as beverages” (emphasis added). It is AHPA’s and IASC’s position that the fact that a product delivers, in its recommended daily serving, amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the U.S., does not make a product a conventional food beverage if no representation is made that the product is specifically intended to meet total daily fluid intake levels, e.g., “a serving of XXX supplement will provide XX% of your daily fluid intake needs.”

Similarly, the draft guidance states, “Product or brand names that use conventional food terms such as ‘beverage,’ ‘drink,’ ‘water,’ ‘juice,’ or similar terms represent the

*product* as a conventional food” (emphasis added). Again, it is AHPA’s and IASC’s position that the use of such terms must be considered in the context of a product’s label, labeling and advertising before it can be determined if a liquid product using such terms is being represented for use as a conventional food. AHPA and IASC therefore propose that both of the last cited sentences should be rewritten in language that is similar to the sentence on a product’s name, and specifically as follows:

- “Suggesting through recommended daily intake that a liquid product is intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the U.S. can represent the product for use as a beverage.”
- “Using a conventional food term such as ‘beverage,’ ‘drink,’ ‘water,’ ‘juice,’ or similar terms may, in the context of the product’s label, label and marketing, represent the product for use as a conventional food.”

These changes are important because the draft guidance does not provide any information to indicate that consumers are presently confused or misled by dietary supplements in conventional food form. Nor has FDA provided evidence that any one of the factors discussed in the draft guidance has any more weight than any of the others or that any benefit to consumers that would flow from the establishment of further criteria to distinguish dietary supplements from conventional foods from those already established by the requirement for a Supplement Facts box versus a Nutrition Facts box to provide nutrition information and the requirement that the principal display panel declare that a dietary supplement is a “supplement.” Moreover, since DSHEA unequivocally authorized dietary supplements in conventional food forms, the burden on FDA would be substantial to establish that a product plainly and unequivocally labeled as a dietary supplement is in fact represented as a conventional food.

**There is no regulatory standard for total daily fluid intake, and FDA’s estimate is based on a single analysis and is lower than other estimates**

There is no established Recommended Daily Intake (RDI) or Daily Value (DV) for daily fluid intake. Accordingly, it is surprising that the draft guidance would take the position that whether a product is represented for use as a conventional food can be predicated on a number selected by its authors as authoritative on this point. This draft guidance is not the proper forum for FDA to establish a daily fluid intake amount, and the agency should instead initiate notice and comment rulemaking if there is a need for such a regulation.

AHPA and IASC have nevertheless reviewed the quantitative estimate of fluid intake provided by the agency in the draft. The draft guidance states that the average total daily drinking fluid intake is about 1.2 liters per person. The draft cites a single

reference for this estimate, identified as “Foods Analysis and Residue Evaluation Program (FARE), Version 8.50, Consumption Analysis: Distribution and Means Analysis based on NHANES 2005-2006.” AHPA and IASC note that an apparently similar or identical analysis accompanied letters issued by FDA on November 30, 2009 as responses to two separate notifications submitted by Shannon Minerals, Inc. with regard to ingredients identified as new dietary ingredients.<sup>12</sup> This analysis is in the form of a memorandum from an FDA review chemist, and states:

“The analysis was completed using the Foods Analysis and Residue Evaluation Program (FARE), Version 8.50, Consumption Analysis: Distribution and Means Analysis, purchased under license by CFSAN from Exponent Inc. The data used in the assessment was taken from the 2005-06 National Health and Nutrition Examination Survey (NHANES). The beverages considered in this estimate include soft drinks, fruit juice and fruit drinks, sports drinks, lemonade and other “ades”, milk and milk-based beverages, coffee and coffee drinks, tea (hot and iced), energy drinks, and drinking water (tap, bottled, non-carbonated, fruit flavored, sweetened with low calorie or no calorie sweetener, with added vitamins and minerals). This estimate does not include fluid Intake from foods such as soups and sauces. Based on the results from this analysis, OFAS estimates that the average intake of drinking fluid for the U.S. population (2+ years old) is approximately 1.2 liters per person per day.”

AHPA and IASC can neither confirm nor deny the accuracy of this analysis and the resulting estimate. AHPA and IASC note, however, that other analyses of total U.S. per person daily drinking fluid intake have been calculated to produce higher estimates than 1.2 liters.

For example, significant attention has been paid to the consumption of tap water and other fluids in pregnant women to evaluate the exposure of pregnant women to chlorination disinfection by-products. Interviews with 71 pregnant and 43 non-pregnant women attending health clinics in Colorado found the average daily consumption of tap water, including tap water used to prepare hot and cold beverages (calculated using only direct glasses of water consumed and beverages made with tap water; no canned beverages, milk, or alcoholic beverages were included with the calculation<sup>13</sup>) to be 3.4 liters in pregnant women and 3.0 liters in non-pregnant women.<sup>14</sup> Another study involving 34 pregnant women identified as patients of a clinic in North Carolina and the male partners of 33 of these subjects recorded mean daily intake of total water, calculated from all consumed beverages, of 1.86 liters and 1.68 liters in the women

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<sup>12</sup> Levy DD (Food and Drug Administration) to O'Mara B (Shannon Minerals Ltd.); November 30, 2009.

<sup>13</sup> Personal communication, R Zender; January 21, 2010.

<sup>14</sup> Zender R, Bachand AM, Reif JS. 2001. Exposure to tap water during pregnancy. *J Expo Anal Environ Epidemiol* 11(3):224-30.

and men, respectively.<sup>15</sup> Though outside of the United States, a study that relied on seven day diaries to obtain information found the mean daily consumption of fluids by 47 pregnant women in Central London to be 2.7 liters.<sup>16</sup>

In approaches that are apparently similar to the reference cited by FDA in the draft guidance, other analyses of data from NHANES have been conducted to estimate total daily fluid intake in the United States. The Institute of Medicine recorded the mean usual daily intake of drinking and beverage water (stated to mean “the sum of plain drinking (tap) water and the water content of all beverages consumed (including water from foods reported in a beverage combination)”) in the U.S., based on 28,178 individuals included in NHANES III (1988-1994), to be 2.38 liters.<sup>17</sup> And using data from the 1999-2000 and 2001-2002 NHANES surveys, the Milk Processor Education Program issued their “What America Drinks” report in which it was stated that average daily fluid was calculated to be ~2.13 liters.<sup>18</sup>

Based on the data provided here, if any final guidance includes a reference to the average total daily drinking fluid intake per person that amount should be expressed as a range rather than as a specific and definitive number, unless the agency has evidence that all of the above references (and others not cited here) are inaccurate.

**The recommended daily volume of a liquid product does not in and of itself establish that the product is represented for use as a food**

As already noted, the draft guidance states, “Liquid products that suggest through their serving size, packaging, or recommended daily intake that they are intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the U.S., are represented as beverages.” Also already noted are the positions of AHPA and IASC that a product that delivers, in its recommended daily serving, a fluid amount equal to or approaching the normal volume of total daily fluid intake does not necessarily establish or represent the product as a conventional food beverage; and that the language of the draft guidance should be revised to establish this factor as one that may be considered in determining whether a liquid product is marketed as a conventional food or as a dietary supplement, but only if such representation refers specifically to daily fluid intakes.

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<sup>15</sup> Shomokura GA, Savitz DA, Symanski E. 1998. Assessment of water use for estimating exposure to tap water contaminants. *Environ Health Perspect* 106(2):55-9.

<sup>16</sup> Kaur, S. *et al.* 2004. Exposure of pregnant women to tap water related activities. *Occup Environ Med* 61:454-60.

<sup>17</sup> Institute of Medicine of the National Academies, Food and Nutrition Board, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Panel on Dietary Reference Intakes for Electrolytes and Water. 2005. *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*. Washington, DC: National Academies Press. Table D-3 (p. 500).

AHPA and IASC are also aware that FDA sent letters on November 30, 2009 in response to two new dietary ingredient notifications submitted in September 2005 by Shannon Minerals Ltd.<sup>19</sup> In these letters the agency stated that each of two cited products “is represented as conventional food because of its packaging and the volume in which it is intended to be consumed.” It therefore appears that the agency has determined after over four years consideration that the factor of volume alone is conclusive in determining whether a liquid product is represented for use as a beverage food. Not only is this determination inconsistent with the fact that a dietary supplement marketer is entitled to establish the serving size of its product, it ignores the history of dietary supplements that are mixed with water or other liquids. Mainly in the sports nutrition category, these products have always been marketed as dietary supplements and may now be pre-mixed in 8 oz or other “food familiar” sizes. This change of form and amount does not suddenly cause these traditional supplement products to be transformed into foods.

**The guidance should consistently use the term “represented for use as” rather than “represented as”**

FDA accurately cites the statutory restriction against dietary supplements being “represented for use as a conventional food or as a sole item of a meal or the diet” (emphasis added). Yet the draft guidance uses the terms, “represented as conventional food [or foods];” “represent the product [or products] as conventional food [or foods];” and “represented as beverages” in numerous places therein.

AHPA and IASC are concerned that failure to use the exact relevant statutory language could result in confusion. This is especially possible since the draft guidance refers to various liquid product factors, such as its name, packaging, serving size, and recommended conditions of use as “representations” about a product. AHPA and IASC therefore suggest that any final guidance replace any of the uses identified above with phrases that include the words “for use,” that is, as “represented for use as conventional food [or foods];” “represent the product [or products] for use as conventional food [or foods];” and “represented for use as beverages.”

**The draft guidance documents if unrevised would constitute *de facto* rulemaking**

AHPA and IASC do not believe that significant changes in regulatory policy should be implemented through a guidance document.

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<sup>18</sup> Weinraub M. January 8, 2007. Liquids make of 22 percent of American diet: study. *Reuters*. Accessed on January 18, 2010 at <http://www.reuters.com/article/idUSN0529211820070108>.

As discussed elsewhere in these comments, FDA has previously addressed the distinction between dietary supplements and conventional food in detail in its promulgation of labeling regulations for dietary supplements. As part of its analysis that accompanied both a draft regulation in December 1995<sup>20</sup> and final rules in September 1997,<sup>21</sup> FDA clearly established that “a dietary supplement may be a product with physical attributes (e.g., product size, shape, taste, packaging) that are essentially the same as a conventional food, so long as it is not represented for use as a conventional food.”<sup>22</sup> Thus, for more than a decade, industry has operated under a clearly enunciated policy communicated through the notice and comment rulemaking process.

AHPA and the IASC believe that the draft guidance represents new and original thinking by the agency that is in direct opposition to prior policy provided to industry through the above-cited rulemaking. AHPA and IASC respectfully submit that it is inappropriate for FDA to announce a substantive change in this policy through a guidance document instead of through notice and comment rulemaking and opportunity for judicial review.

The comments submitted here have provided specific suggestions to amend the draft guidance. If these suggestions are not accepted by the agency in developing final guidance on the issues addressed therein, AHPA and IASC believe that the issuance of final and unamended guidance would constitute *de facto* rulemaking. Such an outcome would be contrary to the agency’s obligation under the Administrative Procedure Act to rely on notice and comment rulemaking any time it publishes a substantive rule that has general applicability to any regulated industry, or makes statements of general policy or interpretations of the general applicability of existing rules or policies already formulated or adopted by the agency.<sup>23</sup> Federal agency actions designed to circumvent this requirement have led to an excessive reliance on what is in essence rulemaking by guidance, and have been rejected by the DC Circuit Court of Appeals.<sup>24</sup>

AHPA and IASC believe that publication of the draft guidance without substantive amendment in accordance with the comments submitted herein would create precisely

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<sup>19</sup> See Note 12, *Supra*.

<sup>20</sup> See Note 2, *Supra*.

<sup>21</sup> See Note 3 and 8, *Supra*.

<sup>22</sup> See Note 9, *Supra*.

<sup>23</sup> 5 U.S.C. §§ 552(a)(1)(D) and 553.

<sup>24</sup> *Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015 (D.C. Cir. 2000).

the situation which led to the court decision referenced above, which struck down overreaching guidance issued by the Environmental Protection agency. The court stated:

“Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. With the advent of the Internet, the agency does not need these official publications to ensure widespread circulation; it can inform those affected simply by posting its new guidance or memoranda or policy statement on its web site. An agency operating in this way gains a large advantage. ‘It can issue or amend its real rules, i.e., its interpretative rules and policy statements, quickly and inexpensively without following any statutorily prescribed procedures.’ The agency may also think there is another advantage--immunizing its lawmaking from judicial review.”<sup>25</sup>

### Conclusion

AHPA and IASC have provided here significant comments on a number of elements of FDA’s draft guidance, and appreciate the opportunity to do so. Both organizations sincerely request that these comments be seriously considered should the agency proceed to issue a final guidance on this matter, and are available to discuss any of the issues raised here.

Respectfully submitted,



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<sup>25</sup> Id. at 1020 (internal citations omitted).



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