

FDA notes that the agency has used certain criteria such as disqualifying or disclosure levels and minimum "qualifying" criteria to ensure that foods that bear a health claim fit within the context of a healthy diet and contain adequate amounts of the substance of interest. Given the absence of these types of criteria for dietary guidance statements, how can FDA ensure that recommendations for making food or substance "substitutions" or "replacements" are not misleading? FDA requests comments on how such statements can be provided for in a way that is based on sound science and is helpful and nonmisleading to consumers. Moreover, FDA requests comments on whether and how recommendations to make dietary substitutions or replacements can, or should, be differentiated from claims about the effects of biologically active substances for the purposes of food labeling and appropriate consumer communication.

4. Dietary Guidance on Food Labels

FDA is seeking comment on dietary guidance statements on food labels generally and on approaches appropriate for FDA to consider under its statutory authorities. As part of this consideration, FDA is requesting comments on whether providing a list of dietary guidance statements that FDA recommends for inclusion on food labels would be desirable or useful to manufacturers. In addition, FDA is requesting comments on these topics: (1) Whether and how the agency should partner with other Federal agencies to identify and agree upon recommended dietary guidance statements for food labeling, (2) the appropriate criteria for evaluating the scientific validity of dietary guidance statements that appear on products in the marketplace, and (3) whether and how the agency should address dietary guidance statements from non-federal sources (e.g., States, trade associations, professional associations, etc.).

IV. Future Analysis of Benefits and Costs

For the agency's future analysis of benefits and costs of the regulatory options for qualified health claims, FDA requests comments, including available data, on the following questions:

- What effects do health claims have on consumer purchases of foods and dietary supplements? What effects do health claims have on the total diet?
- Is there a difference between consumers' willingness to buy products with qualified health claims and

consumers' willingness to buy products with health claims based on SSA?

- What effects would the different qualifying phrases described in the interim procedures for qualified health claims guidance¹⁶ (Ref. 3) and the Task Force report (Ref. 4) have on the willingness of consumers to buy the products containing the claims? Is there evidence that consumers would find the differences among qualifying phrases to be substantial?
- What types of foods and dietary supplements are most likely to use qualified health claims in their labeling? What types of claims are most likely to be used by those products?
- What types of existing products will manufacturers re-formulate in order to be able to make qualified health claims? What types of claims are most likely to lead to re-formulation?
- What new products might be developed in response to qualified health claims?
- Would any of the regulatory options discussed in this ANPRM have a significant effect on small businesses or other small entities?
- What additional research should FDA, other government agencies, or other organizations sponsor to answer these questions?

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal Government holidays. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. Task Force Final Report, "Consumer Health Information for Better Nutrition Initiative" (July 10, 2003) (Internet addresses: <http://www.fda.gov/oc/mcclellan/chbn.html> or <http://www.fda.gov/ohrms/dockets/default.htm>).

2. "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for

¹⁶ The guidance identifies three different qualifying phrases (or standardized qualifying language) for qualified health claims. These phrases are used according to a scientific ranking assigned to the claim (which is discussed in the interim evidence-based ranking system guidance (Ref. 2)). FDA has categorized these phrases as B, C, and D, as follows: *Category B*: "Although there is scientific evidence supporting the claim, the evidence is not conclusive."; *Category C*: "Some scientific evidence suggests * * * however, FDA has determined that this evidence is limited and not conclusive."; *Category D*: "Very limited and preliminary scientific research suggests * * * FDA concludes that there is little scientific evidence supporting this claim." The Task Force report lists the same three qualifying phrases in its overview of the interim procedures for qualified health claims guidance.

Scientific Data" (Internet addresses: <http://www.cfsan.fda.gov/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.htm>).

3. "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (Internet addresses: <http://www.cfsan.fda.gov/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.htm>).

4. Task Force Final Report, Attachment A: "Possible Regulatory Frameworks for Qualified Health Claims" (Internet addresses: <http://www.fda.gov/oc/mcclellan/chbn.html> or <http://www.fda.gov/ohrms/dockets/default.htm>).

5. CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements, "Dietary Guidance Message About Fruits and Vegetables" (July 29, 2003; revised August 28, 2003) (Internet address: <http://www.cfsan.fda.gov/~dms/lab-dg.html>).

VI. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1304, 1306, and 1310

[Docket No. DEA-234P]

RIN 1117-AA71

Recordkeeping and Reporting Requirements for Drug Products Containing Gamma-Hydroxybutyric Acid (GHB)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA proposes to amend its regulations to require additional recordkeeping and reporting requirements for drug products containing gamma-hydroxybutyric acid (GHB) for which an application has been approved under the Federal Food, Drug, and Cosmetic Act. DEA proposes