Docket No. 96N-0417

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

American Herbal Products Association

ON THE PROPOSED RULE FOR

Current Good Manufacturing Practice

in Manufacturing, Packing or Holding

Dietary Ingredients and Dietary Supplements

Part 3 of 3:

Comments on errors and misrepresentations in the March 13, 2003 *Federal Register* notice

August 11, 2003

The American Herbal Products Association ("AHPA") is filing comments in three separate parts in the matter of FDA's proposed rule for current good manufacturing practice in manufacturing, packing, and holding dietary ingredients and dietary supplements ("the Proposed Rule") as published in the *Federal Register* on March 13, 2003.

"Part 1 of 3" of AHPA's comments provides general and specific comments to the Proposed Rule and also includes background information and a statement of the interest that AHPA and its members have in the Proposed Rule. "Part 2 of 3" of AHPA's comments consists of a "redline" edit of the Proposed Rule that constitutes AHPA's proposed revision to the Proposed Rule. The comments submitted in these pages constitute "Part 3 of 3," a commentary on certain of the errors and misrepresentations that AHPA has observed in the March 13 *Federal Register* notice that accompanied the Proposed Rule.

Errors and misrepresentations in the March 13, 2003 *Federal Register* notice

AHPA has taken an active role since the passage of DSHEA to support the development of cGMP regulations for dietary supplements. This role included participation in the development of the Industry Draft and service by Michael McGuffin, now AHPA's President and at that time a member of AHPA's Board of Trustees, as a member of the FDA Food Advisory Committee's Working Group for Good Manufacturing Practices for Dietary Supplements. In addition, AHPA has presented a consistent public message in support of such regulation.

AHPA was therefore disappointed, in reading the March 13, 2003 *Federal Register* notice in which the Proposed Rule was published, that the agency chose to disregard the efforts of industry over the last several years. Except for a brief acknowledgement of receipt of the Industry Draft and also of the cGMP developed by the National Nutritional Foods Association, the preamble to the Proposed Rule ignores the nearly decade-long support, and even impatience, that has been consistently communicated by industry. Any reader who is not familiar with the actual facts would be led to believe that the Proposed Rule is the outcome of FDA's realization of a need, when in fact the industry and a few

Federal legislators have been much more insistent than the agency of the need for dietary supplement cGMP.

Of much more concern, however, are the blatant errors and misrepresentations that are included in the March 13, 2003 preamble, especially in Section E.1, titled "Why are cGMP needed?" This section consists of a review of an article published in *Prevention* magazine in 1999 and of nine "examples" that "illustrate the wide range of dietary ingredient and dietary supplement adulteration caused by manufacturing, packaging or holding practices" that "demonstrate why cGMP are necessary to protect public health."

The *Prevention* article offers absolutely no rationale as to why cGMP are needed for dietary supplements. The specific citations from this document that FDA chose to highlight under the heading, "CGMPs help protect the public health" have no relevance to an honest evaluation of the role that cGMP for dietary supplements would actually play in protecting the public health. If the statistic that "[O]nly 41% of the surveyed consumers who use vitamins and minerals[1] think they are very safe," is, in fact, accurate, how does that fact support any belief that the cGMP for dietary supplements, and the Proposed Rule in particular, will protect the public health? What is the value of a statistic that records that 74 percent of the public "reported that they think that the government should be *more* involved in ensuring that these products are safe and do what they claim to do," when 50 percent of the population believes, *erroneously*, that the government does not regulate this class of goods, and another 16 percent report that they do not know if there is government regulation of dietary supplements?

An examination of the nine "examples" that purportedly "demonstrate why cGMP are necessary to protect public health" can only lead to suspicion about FDA's ability to be straightforward about the goods marketed by the particular "stakeholder" that is the dietary supplement industry, or else to an assumption

[1] The agency's description of this population is inconsistent with the *Prevention* document, which identifies this group as "41 percent of the nation's consumers." There is nothing in the document that supports FDA's representation of this group as a percentage of only that subpopulation that uses vitamins and minerals, and it is just as likely that the 15 percent of the total population who do not use supplements were also included in these calculations.

that the agency itself does not understand current regulations. **Each example cited is an example of a failure to conform to an existing regulation for which FDA has current enforcement authority.** None of these given examples actually provide any demonstration for the need for new cGMP regulation. Each of the examples – use of misidentified ingredients (whether or not of public health significance); insanitary conditions; contamination with lead, glass or pathogens; sub- or super-potent products; undeclared ingredients; failure to meet label claims – are illegal under current regulations. Ironically, the agency passively acknowledged this fact by reporting that numerous of the already illegal manufacturing failures had been subjected to voluntary recall under current regulations and authority.

AHPA wishes to comment in some detail on two of these nine examples. FDA states that our organization conducted a survey in 1998 to identify commonly adulterated botanicals. While this is accurate, the resultant publication, *Survey on Botanical Adulteration*, identified 45 botanicals for which one or more companies provided information as to possible adulteration, and for 30 of these plants only one such report was received. Nevertheless, the agency represented all of these plants as "commonly adulterated with contaminants." This is a blatant misrepresentation of AHPA's effort to catalogue information that could meaningfully contribute to product identification. To represent a single report as "commonly adulterated" is false. Such misrepresentation also failed to convey the fact that the companies that participated in this survey were fully aware of the potential for adulteration and that each of the participating firms identified steps that had been adopted to assure that the potential adulterant was not inadvertently used in manufacturing. To turn this responsible effort on the part of a trade association into an illustration of the "wide range of dietary ingredient and dietary supplement adulteration" is unappreciated. It should also be noted that existing regulations already prohibit the inclusion of any of the potential adulterants identified in this text, or any other misidentified ingredient, and that FDA has today full authority to enforce against adulterated supplements.

Another of these purportedly rule-supporting examples involved the use of what the agency identified in the text of the March 13, 2003 *Federal Register*

notice as "non-food grade chemicals." Any uninformed reader of this government-published document would understandably find this to be troubling, at the least. Hidden in the details of the actual reference to support this accusation, however, is a fact that might not be meaningful to an uninformed reader: the non-food grade chemical that FDA referred to here was gamma-butyrolactone (GHB)! GHB is illegal as an ingredient in any food or dietary supplement!! This was true on the date of the publication of the reference to which FDA referred (which, in fact, correctly states, "Although labeled as dietary supplements, GBL-containing products are illegally marketed, unapproved new drugs" [2]), it remains true today, and it will be true after publication of the Final Rule – thus, this example has nothing to do with current good manufacturing practice. It is offensive to the dietary supplement "stakeholder" to identify the illegal marketing of this ingredient as having any relationship to the Proposed Rule.

AHPA strongly believes that the Food and Drug Administration must expend real and significant efforts to overcome the misperceptions that have resulted from the erroneous implication that these nine examples have communicated to the public. AHPA believes that the agency should issue a formal correction of these inaccurate statements, and specifically requests that the agency apologize for misrepresenting the information included in AHPA's *Survey on Botanical Adulteration.*

Until such time as compliance with the Final Rule is required, all manufacturers, packers and holders of dietary supplement are legally bound to comply with cGMP for food as codified in 21 CFR 110 as well as the relevant labeling regulations in 21 CFR 101.4, 101.9 and 101.36 and the Federal Food, Drug, and Cosmetic Act itself. As such, products must not contain misidentified ingredients and undeclared ingredients (whether or not of public health significance); facilities must be maintained under sanitary conditions; products must be free of contamination with lead, glass or pathogens, and must not be

[2] "Adverse Events Associated with Ingestion of Gamma-Butyrolactone: Minnesota, New Mexico, and Texas, 1998-1999," *MMWR Weekly*, 48:07, pp. 137-140, February 26, 1999.

sub- or super-potent products or fail to meet label claims in any particular. AHPA believes that the United States Food and Drug Administration is fully aware of its current authority and requests that the agency acknowledge its authority in these matters.

Conclusions

In spite of AHPA's stated concerns about these misrepresentations, AHPA and its members continue to support the establishment of cGMP that are specific to dietary supplements. AHPA's support for new rules stems from a belief that, although full enforcement of the current cGMP would protect the public health, new rules can more accurately reflect practices that are more representative of current industry practices and can more fully implement current industry thinking as to what constitutes good manufacturing practice for this diverse and important class of goods.

AHPA appreciates the opportunity to provide these comments to the Proposed Rule for current good manufacturing practice in manufacturing, packing, and holding dietary ingredients and dietary supplements hopes that the agency will treat these comments and those provided as "Part 1 of 3" and "Part 2 of 3" on this date seriously.

Respectfully submitted,

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