AARP

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August 11, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
12420 Parklawn Drive
Rockville, MD 20852

Re: Docket Nos. 96N-0417
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements
68 Fed. Reg. 12158 (March 13, 2003)

AARP appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule establishing quality standards for dietary supplements. According to our own survey data,[1] a majority of persons 50 and older (62 percent) take some type of dietary supplement on a regular basis. With so many people taking these products to reduce the risk of certain diseases and improve their overall health, it is important that there be reasonable assurances of safety, efficacy, and quality.

The proposed regulations address this last issue by establishing requirements aimed at ensuring that supplement products are not contaminated and that they contain the ingredients and the amounts claimed on the product labels. We hope that safety and efficacy will be areas of future FDA attention as more information comes available.

Our comments will address only two aspects of the proposed rule: consumer complaints and expiration dating. Most of the proposed Current Good Manufacturing Practice (CGMP) regulations govern the quality of manufacturing processes and involve technical issues best addressed by the manufacturers and the agency. Our only comment regarding these issues is a request that FDA finalize the rule as soon as possible. It has been nearly a decade since the Dietary Supplement Health and Education Act authorized the agency to adopt CGMP regulations and we believe that consumers deserve to have quality controls for supplement products in place as soon as possible.

96N-0417 C 173

[1] Attached to this comment is a copy of our report on the survey results.

Consumer Complaints

In general, we support the proposed approach to the handling of consumer complaints by supplement manufacturers. Consumer complaints can be helpful in alerting companies to possible manufacturing and safety problems associated with dietary ingredients or supplement products. These complaints address a possible failure to meet *any* of the requirements of the CGMP regulations, which, if not met, "*may* result in a *possible* risk of illness or injury." [emphasis added]

Under the proposal, manufacturers would be required to keep a written record of every consumer complaint that is related to good manufacturing practices, whether it was conveyed through regular mail, electronic mail, or any other form of written or oral communication. This record would include all information that would allow a quality control unit to determine whether an investigation of the complaint is necessary.

We believe that the proposed procedure for handling complaints needs strengthening. First, rather than just "suggesting" that companies report consumer complaint and investigation results to FDA, we believe that the agency should require them to do so. This is because the post-market surveillance system for supplements is a passive one (i.e., relies on information that is sent to, not collected by, FDA). These complaint reports are a major source of information regarding potential problems with supplements and may be the only way for FDA to learn about these problems. In particular, these reports may enable FDA to identify a problem that affects more than one plant (e.g., a dietary ingredient that is used by a number of manufacturers that is contaminated).

Second, we are concerned about what happens to complaints that may address the underlying safety of a product but are not related to its processing or packaging. We urge FDA to require that any such complaint, if received by a company's CGMP complaint department, be referred to FDA's MedWatch program. The company would not necessarily be required to undertake an extensive investigation of this complaint; it would merely be required to transmit the initial information to the FDA, using the MedWatch form. The agency would then follow up, if necessary.

FDA also requests comment on whether manufacturers and other affected entities should be required to establish written procedures relating to the handling of consumer complaints. Given the fact that complaints may relate to serious illness or injury, we believe that a written procedure that sets out exactly what steps need to be taken is the best way to ensure that the essential information is captured.

Expiration Dating

Our dietary supplement survey found that an overwhelming number of respondents (82%) indicated that they would like to see expiration dates on supplement product labels. In the preamble to the proposed rule, FDA tentatively decides that, since the science is "still evolving," it will not propose specific requirements for expiration dating, nor for dissolution, disintegration, and bioavailability.

We understand that it would be premature to establish such requirements. However, given the importance of these issues to product quality and efficacy, we urge the agency to fund, assist in, and encourage research efforts that would lead to the establishment of these requirements.

Thank you for this opportunity to share the views of AARP. If you have any additional questions, please contact Larry White of our Federal Affairs staff at (202) 434-3800.

Sincerely,

David Certner
Director
Federal Affairs