

neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

A. Introduction

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets anyone of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule, if it were to become a final rule, would be a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) defines a major rule for the purpose of congressional review as being likely to cause one or more of the following: an annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U. S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, when final, will be a major rule for the purpose of congressional review.

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

We carry out the cost-benefit analyses required for significant rules in the

Preliminary Regulatory Impact Analysis, in section VII.B of this document. We perform the Initial Regulatory Flexibility Analysis of the effects on the proposed rule on small businesses in section VII.C of this document.

B. Preliminary Regulatory Impact Analysis

1. The Need for the Proposed CGMP Regulations

The proposed CGMP regulations are needed because establishments that manufacture, package, and hold dietary ingredients and dietary supplements may not have sufficient market incentives to use controls to prevent the adulteration and misbranding of dietary ingredients or dietary supplements, including incentives to ensure their identity, purity, quality, strength, and composition (product quality). Manufacturing, packaging, and holding practices that ensure product quality can be costly, so establishments may not adopt them unless required to do so by regulation. Without the proposed regulations consumers of dietary supplements cannot be assured that all establishments are manufacturing dietary supplements in a way that ensures that these products are not adulterated or misbranded.

Manufacturing, packaging, and holding practices can compromise safety if they fail to prevent biological, chemical, and physical contamination, or if the wrong dietary ingredients are used that present an unreasonable risk of illness or injury. Strength (which is the amount of a specific dietary supplement or dietary ingredient in each tablet or capsule) that differs from label statements, missing or extra ingredients, and inconsistency across units of the product are other problems caused by poor manufacturing practices. Products may also be held in insanitary or environmentally inappropriate conditions, or may be physically damaged if stored improperly. Some poor manufacturing practices, such as the use of ingredients that are undeclared, of incorrect strength, or missing altogether result in a misbranded product. The proposed CGMP regulations would establish minimum requirements to ensure that manufacturing, packaging, and holding practices ensure the identity and quality of components, dietary ingredients, and dietary supplements.

Consumers today rely on manufacturer's assurances, existing regulations and statutes (for example, section 402(a)(3) and (a)(4) of the act), and recourse to the legal system to ensure that products are not defective.

Brand names convey some information to consumers about a firm's manufacturing practices. Some private organizations, such as the National Nutritional Foods Association and the USP design minimum product standards or manufacturing requirements. The current act contains some provisions that prevent using putrid substances and insanitary manufacturing practices. In addition, either the threat of litigation or consumers seeking compensation for defective products and adverse health events may create incentives for establishments to adopt good manufacturing practices.

Actions by manufacturers, primarily voluntary quality controls, do not provide sufficiently protective industry-wide minimum requirements for manufacturing, packaging, and holding of dietary ingredients and dietary supplements. Without the proposed regulations, survey evidence shows that products in the dietary supplement market are sorted somewhere between two types:

- Higher-priced products with brand names or industry certification that follow several of the good manufacturing practices proposed here;
- Lower-priced products that contain no private certification or respected brand name and that follow few of the good manufacturing practices that are proposed here.

Without the proposed rule, the current practices do not provide all consumers with safe manufacturing practices or reliable product quality throughout the industry.

The market for dietary supplements is full of information; consumers of dietary supplements must sort through information and misinformation about the properties of these products from magazines, brochures, popular books, television, and a host of other sources. However, the information from these sources deals most often with the claims for the products themselves, not with the steps taken by establishments to protect against contamination or to ensure quality. Private quality control fails to provide industry-wide minimum good manufacturing practices for the following reasons:

- Establishments do not have incentives to disclose information about their own practices, because disclosure that some consumers may perceive to be harmful or undesirable would reduce the demand for their products. Establishments therefore have incentives to withhold information from consumers.
- Businesses normally do not advertise differences in manufacturing