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July 15, 2003
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0434; Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent; 68 Fed. Reg. 19766 (April 22, 2003).

Dear Sir or Madam:

INTRODUCTION

In the Federal Register of April 22, 2003, the Food and Drug Administration (FDA) proposed to withdraw certain advanced notices of proposed rulemakings, proposed rules and other proposed actions that were published in the Federal Register more than five years ago. FDA stated that these proposals are no longer considered viable candidates for final action at this time. Comments were requested by July 21, 2003.

These comments are submitted on behalf of the American Association of Homeopathic Pharmacists (AAHP), the association of the principal manufacturers and distributors of homeopathic drugs in the United States. One of the proposals which FDA intends to withdraw, Docket No. 79P-0265, was published in response to a Citizen Petition filed by the AAHP in 1979 and the issues the proposed rule addressed are as valid today as the day it was published. Accordingly, the AAHP respectfully opposes FDA's proposed action.

HISTORY

The proposal FDA seeks to withdraw is over 20 years old. On July 12, 1979, the AAHP submitted to FDA a Citizen Petition to amend the then-recently adopted Current Good Manufacturing Practice (CGMP) regulations by exempting homeopathic drugs from compliance with certain requirements in 21 C.F.R. § 211.165(a), which requires laboratory testing of finished drug products to determine conformance with established specifications, including identity and strength of each active ingredients, before the products are released for sale.

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In support of its petition, the AAHP noted that it was impractical to require active ingredient testing for finished products because of the highly diluted nature of the active ingredients; that other non-conventional products were exempt from certain impractical requirements; and the singular economic impact that the requirement would have on a unique segment of the pharmaceutical industry.

FDA agreed with the petition and, in the Federal Register of April 1, 1983, 48 Fed. Reg. 14003, proposed to exempt homeopathic drug products from the CGMP requirement for active ingredient identity and strength testing in finished products.

The agency explained that:

FDA has weighed all of the petitioner's contentions, and believes that most of the arguments are well-founded and that the petition should be granted. As explained in detail below, the agency's position is based primarily on the following three factors: First, the agency believes that granting the petition is entirely consistent with the agency's prior recognition of homeopathic drug products as unique entities. Second, the agency is convinced that the benefits to be gained by enforcing the requirement are far outweighed by the potential increase in costs to the industry of conducting the active ingredient tests. Third, the agency believes that the quality controls required by other portions of the CGMP regulations and the requirements of "The Homeopathic Pharmacopoeia of the United States" are sufficient to ensure the quality of homeopathic drug products.

In the preamble to the final CGMP regulations, (comment 357, in the Federal Register of September 29, 1978; 43 FR 45058), FDA formally acknowledged the uniqueness of homeopathic drug products. Accordingly, they were exempted from expiration dating and from complete stability testing due to the imprecise nature of measuring extremely low levels of active ingredients in homeopathic drug substances and because such criteria as potency, absorption, bioavailability, and other measures of effectiveness do not appear to apply to homeopathic drug products. Identical arguments have been presented by the petitioner to support its request. The agency accepts the petitioner's contention that the fundamental justifications for exempting homeopathic drug products from expiration dating and complete stability testing also justifies exempting finished homeopathic drug products from active ingredient testing for identity and strength. Therefore, the agency believes it would be inconsistent with this position to deny the petitioner's request.

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48 Fed Reg. At 14004.

CONCLUSION

The AAHP believes that the passage of time has done nothing to undermine the validity of its arguments, the reasonableness of its request, nor the basis for FDA's announced decision to grant the requested relief. Indeed, the reasonableness of our request was such that FDA as a matter of enforcement discretion permitted homeopathic drug manufacturers to follow the provisions of the proposed rule pending adoption of a final rule:

The agency has determined that because of the nature of the proposed change, it is in the public interest to allow manufacturers of homeopathic drug products to follow the provisions of the proposal pending completion of the rulemaking proceeding. Therefore, homeopathic drug products, on the publication date of this proposal, will no longer be required to comply with the requirement for laboratory determination of identity and strength of each active ingredient in the drug product before release. Pending the receipt of comments on this proposal, and the agency's final decision on this matter, this interim enforcement policy will remain in effect. If the agency determines not to adopt this proposal as a final rule, it will so announce in further rulemaking notices that published in the Federal Register.

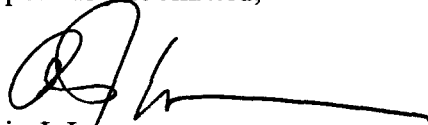
Id. Thus, the interim enforcement policy which has applied for the past 20 years would, by its terms, expire with the publication of a final rule withdrawing the 1983 proposal. Were that to occur, the substantial economic burdens and the absence of public health benefit which formed the basis for the petition and FDA's concurrence, would be visited upon homeopathic drug manufacturers as well as consumers of homeopathic drug products. As there are currently in excess of 1,300 distinct homeopathic drug products, the industry could simply not afford to implement the rule. Furthermore, the technology simply does not exist to identify and quantify the very small amounts of active ingredients present in many homeopathic drug products. Beyond the technical difficulties and the economic impact on manufacturers, the inevitable disappearance of many homeopathic products would have an adverse effect on consumers who have come to rely on those products. In the 20 years since FDA permitted homeopathic drug manufacturers to follow the interim enforcement policy, there has been no reported adverse incident that could be attributed to the lack of certain finished product testing. The AAHP believes that FDA's failure to act on the proposal for 20 years and its claimed new priorities are an insufficient basis to now burden the homeopathic drug industry and consumers with requirements which clearly have been unnecessary to protect the public health.

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Accordingly, FDA should finalize the rulemaking it began -- and endorsed -- in 1983.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Alvin J. Lorman', with a long horizontal line extending to the right.

Alvin J. Lorman
Counsel to the American Association of
Homeopathic Pharmacists