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**PETITION FOR RECONSIDERATION**

**AND FOR STAY OF ACTION**

**Docket Nos. 2002N-0434 and 79P-0265**

To the Commissioner of Food and Drugs:

The undersigned American Association of Homeopathic Pharmacists, Inc. (AAHP), by counsel, submits this Petition for Reconsideration and for Stay of Action concerning that part of Docket No. 2002N-0434 which withdrew a proposed rule originally published in the FEDERAL REGISTER of April 1, 1983, 48 FED. REG. 14003 (Docket No. 79P-0265).

**A. DECISION INVOLVED**

This petition seeks reconsideration and a stay of action on the decision (in the form of a final rule) of the Food and Drug Administration (FDA or the agency), published in the FEDERAL REGISTER of November 26, 2004, 69 FED. REG. 68831, to withdraw the agency's prior proposed rule to exempt homeopathic drugs from compliance with certain final release testing requirements in 21 C.F.R. § 211.165(a).

**B. ACTION REQUESTED**

Since the withdrawal of the proposed rule and accompanying interim enforcement policy has immediate effects on homeopathic drug manufacturers, the AAHP requests that the Commissioner stay the effective date of the rule withdrawing the proposed rule until he rules on this Petition for Reconsideration or until the agency and the industry can agree upon an alternative solution.

**C. STATEMENT OF GROUNDS**

Brussels Charlotte Chicago Cologne Frankfurt Houston London Los Angeles Manchester New York Palo Alto Paris Washington, D.C.  
Independent Mexico City Correspondent: Jauregui, Navarrete, Nader y Rojas, S.C.

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### 1. BACKGROUND

This matter began at the time the agency published its Current Good Manufacturing (cGMP) regulations, 21 C.F.R. Part 211. On July 12, 1979, the AAHP, which represents the principal manufacturers and distributors of homeopathic drugs in the United States, submitted to FDA a Citizen Petition to amend the then-recently adopted 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.

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 cGMP 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.

In the FEDERAL REGISTER, 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

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ingredient testing for identity and strength. Therefore, the agency believes it would be inconsistent with this position to deny the petitioner's request.

48 FED. REG. at 14004.

Indeed, the reasonableness of the AAHP's 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, saying that:

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 published in the Federal Register.

*Id.*

Twenty years later, FDA had not acted on the proposed rule, despite the lack of opposition to the proposal. In the FEDERAL REGISTER of April 22, 2003, 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. As noted above, one of the proposals which FDA intended to withdraw, Docket No. 79P-0265, was published in response to the AAHP 1979 Citizen Petition. The AAHP opposed the withdrawal of the proposal, stating that, "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."

FDA rejected this view. In the final rule published on November 26, 2004, FDA said this (in its entirety) about the withdrawal of the proposed rule:

(Comment) The agency received one comment opposing the withdrawal of this proposed rule which would have exempted homeopathic drugs from the current good manufacturing practice (CGMP) requirements that drug products be tested for identity and strength of each active ingredient prior to release for distribution. The comment expressed concerns about possible changes in our enforcement policy towards final release testing of homeopathic drugs.

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(Response) There may be instances where testing of a homeopathic product for identity and strength of the active ingredients prior to release for distribution would be appropriate and consistent with protection of the public health. For example, in instances where a product includes an active ingredient that at certain levels could be toxic or otherwise pose a public health concern, finished product testing may be appropriate because the testing could identify a significant manufacturing or labeling error. Since requiring this testing when necessary to protect the public health is consistent with FDA's mandate, we are withdrawing the proposed rule.

69 FED. REG. 68831, 68834 (Nov. 26, 2004).

### 2. DISCUSSION

The AAHP believes that FDA's decision to withdraw the proposed rule is incorrect on both public health and legal grounds.

The withdrawal of the proposed rule, and the attendant termination of FDA's enforcement discretion, visits upon homeopathic drug manufacturers as well as consumers of homeopathic drug products the substantial economic burdens and the absence of public health benefit which formed the basis for the petition and FDA's concurrence. As there are currently in excess of 1,300 distinct homeopathic drug products, the industry simply could not afford to implement the rule across the board. Furthermore, the technology simply does not exist to identify and quantify the very small amounts of active ingredients present in many homeopathic drug products.

While FDA might respond that it did not state that it would require finished product testing for all 1,300 homeopathic products, that response provides little comfort. What FDA said was that, "There **may** be instances where testing of a homeopathic product for identity and strength of the active ingredients prior to release for distribution would be appropriate and consistent with protection of the public health." 69 FED. REG. at 68834 (emphasis added). As an example, FDA said that an active ingredient which is toxic or otherwise presents a health concern at the level present in the finished product, should be tested to protect the public health.

There are two fundamental problems with this position, however. First, an unsupported reference to "instances" where testing would be appropriate is hardly a reasoned explanation for a complete about-face from its earlier position. FDA spent several paragraphs in 1983 explaining why homeopathic need not undergo finished product testing; today it reverses itself in three sentences. The problem with this cavalier reversal is that history has demonstrated that the Agency's original position was correct. 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. Indeed, it is hard to imagine that there is a homeopathic drug product available over-the-counter which would contain an active ingredient at a level that might be toxic or otherwise unhealthy. This is so because the Homeopathic Pharmacopoeia of the United States establishes minimum dilution (potency) levels for the over-the-counter (OTC) sale of homeopathic drugs. Drugs which "might" present the risks FDA hypothesized are not available OTC

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by definition, and it is unlikely that they are manufactured (as opposed to compounded) on a commercial basis as prescription drugs. 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 shown to be unnecessary to protect the public health.

Second, the withdrawal of the proposed rule and the interim enforcement policy means that regulatory certainty is being replaced by uncertainty, both for industry and for the agency. In the absence of clear guidance as to what constitutes an active ingredient at a level that "may" justify finished product testing for toxicity or "other" health concerns, industry is left to guess at what the next FDA inspection will reveal. And, of course, since FDA's investigators have no more guidance than industry, they, too, will be faced with the kind of *ad hoc* decision-making which is the bane of regulated industry.

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.

The agency's withdrawal of the proposed rule and associated interim compliance policy is also faulty as a matter of law. While an agency is certainly permitted to change its mind about an issue, doing so requires more of an explanation than has been provided.

While "[a]n agency may always change its mind and alter its policies," when "an agency reverses its policy . . . it must supply a reasoned analysis for the change." *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F.Supp. 837, 845 (D.C.C. 1992)(citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. 29, 41 (1983)); *Advanced Micro Devices v. Civil Aeronautics Board*, 742 F.2d 1520, 1542 (D.C. Cir. 1984)("an agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.")(quoting *Greater Boston Tel. Corp. v. FCC*, 444 F. 2d 841, 852 (D.C. Cir. 1970)). *Accord Dimension Financial Corp. v. Board of Governors*, 744 F.2d 1402, 1409 (10th Cir.), *aff'd*, 474 U.S. 361 (1986)("when an agency radically changes its position . . . the agency must clearly articulate the basis for the change."); *St. James Hosp. v. Heckler*, 760 F.2d 1460, 1472 (7th Cir. 1985)(concluding that the Secretary of Health and Human Services violated the cost-shifting prohibition of the Medicare Act by changing "established policy" without adequate factual support in the record.).

The need to explicitly state the basis for the agency's change of position is not just for the benefit of those affected; a court reviewing the agency's action needs a basis on which to conduct that review. *See Atchison, Topeka & Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973)("Whatever the ground for departure from prior norms . . . it must be clearly set forth so that the reviewing court may understand the basis of the agency's action and so may judge the consistency of the action with the agency's mandate.").

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FDA's explanation for withdrawing the proposed rule does not begin to satisfy the standards required by reviewing courts. In 1983, FDA found that:

- “[T]he agency believes that granting the petition is entirely consistent with the agency’s prior recognition of homeopathic drug products as unique entities.”
- “[T]he 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.”
- “[T]he 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.”

48 Fed. Reg. at 14004.

The agency has cited no changed circumstances to reverse its prior decision; it did not dispute the factual contentions of the AAHP; and, most tellingly, it neither acknowledged nor rebutted its prior conclusion that the requested relief has been justified. Accordingly, the agency’s decision cannot stand.

**4. CONCLUSION**

For the reasons set forth above, the Commissioner should stay the effectiveness of the final rule published on November 26, 2004, insofar as it withdraws the proposed rule in Docket No. 79P-0265, and reconsider and reverse that decision. Alternatively, the Commissioner should stay the decision and create guidance which sets forth, by class or individually, those homeopathic drug products which are subject to the final release testing requirements. The AAHP would welcome an opportunity to meet with the agency to discuss identifying such drug products.

Respectfully submitted,

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By Counsel

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