

February 28, 2000

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

Re: FDA Proposal to Revise the Citizen Petition Regulation,  
64 Fed. Reg. 66822 (November 30, 1999)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) submits these comments on the proposal published by the Food and Drug Administration (FDA) in 64 Fed. Reg. 66822 (November 30, 1999) to revise its citizen petition regulations, 21 C.F.R. § 10.25 and 21 C.F.R. § 10.30.

## **I. INTRODUCTION**

FDA regulations permit any interested person to petition the agency, requesting any action -- that the agency issue, amend, or revoke a regulation; that it issue, amend, or revoke an order; or that it take or refrain from taking any other administrative action.<sup>1</sup> The agency must respond within 180 days of receipt of the petition, and ultimately must "rule" upon the petition.<sup>2</sup> That ruling is final agency action in the matter, which can then be challenged in court. FDA regulations create and define the

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<sup>1</sup> 21 C.F.R. § 10.25.

<sup>2</sup> 21 C.F.R. § 10.30(e).

administrative record in a petition proceeding, for purposes of that review.<sup>3</sup> This citizen petition process has been in place at FDA for twenty-five years.<sup>4</sup>

In November 1999, FDA proposed substantially to limit the citizen petition process.<sup>5</sup> Under the proposed regulations, FDA would not consider petitions to issue an order or to amend a pending order.<sup>6</sup> Requests that the agency issue, amend, or repeal a rule would have to pertain to "a subject that is appropriately and ordinarily addressed by regulation."<sup>7</sup> FDA would also eliminate the provision that a petitioner may request any administrative action, requiring instead that an FDA regulation authorize citizen petitions on the topic.<sup>8</sup> Under the proposed rule, therefore, a citizen petition could only be filed if (a) it requested the issuance, amendment, or repeal of a regulation; (b) an existing regulation authorized petitions on the topic; or (c) it pertained to an already-issued order. In addition, FDA could refer for "other administration action" (including treatment as correspondence) any petition that involves issues that are the subject of a pending or future proceeding, that presents data or issues specific to a particular product

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<sup>3</sup> 21 C.F.R. § 10.30(i).

<sup>4</sup> 40 Fed. Reg. 40682 (September 3, 1975) (proposed rule); 42 Fed. Reg. 4680 (January 25, 1977) (final rule).

<sup>5</sup> 64 Fed. Reg. 66822 (November 30, 1999).

<sup>6</sup> *Id.*, at 66823.

<sup>7</sup> *Id.*

<sup>8</sup> For instance, FDA states, 21 C.F.R. § 861.38(b)(2) expressly allows a person to file a citizen petition to establish, amend, or revoke a performance standard. 64 Fed. Reg.

or class of products, or that does not involve a significant public health or consumer protection issue.<sup>9</sup>

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national association representing manufacturers and distributors of over-the-counter (OTC) drugs and dietary supplements. CHPA members account for over 90 percent of the retail sales of OTC drugs in the United States. CHPA has been a major participant in every aspect of the OTC Drug Review process since its inception in 1972.

CHPA opposes the proposed regulations because they appear to preclude the introduction of new data and information in the OTC Drug Review more than twelve months after a tentative final monograph has issued. Moreover, under the proposed regulations many petitions raising issues of importance to the OTC drug industry could be rejected or treated as correspondence. The alternatives to petitioning discussed in the preamble to the proposal are inadequate to ensure that the agency will engage in dialogue about these issues. CHPA also endorses the comments on this proposal filed by the Cosmetic, Toiletry, and Fragrance Association.

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at 66824. The new regulation does not address the possibility that the federal Food, Drug, and Cosmetic Act might authorize citizen petitions on a particular topic.

<sup>9</sup> 64 Fed. Reg. at 66824, 66828.

## II. COMMENTS

### A. **The Proposed Regulations May Prevent FDA from Taking into Account New Data and New Information During the OTC Drug Review.**

#### 1. **The Citizen Petition Process Has Been Used Extensively to Supplement the Administrative Record in the OTC Drug Review.**

In 1972, in response to the Drug Amendments of 1962,<sup>10</sup> FDA began to review the hundreds of thousands of over-the-counter drugs marketed in the United States prior to 1962. FDA classified these drugs into therapeutic categories and initiated a rulemaking for each category to determine the conditions of use (active ingredients, indications, dosage forms, dosage strengths, routes of administration, and active ingredient combinations) under which products in that category would be safe, effective, and not misbranded. FDA's initial regulations divided OTC drugs into twenty six categories. The initial twenty-six categories were later subdivided into 88 subcategories, each the subject of a separate rulemaking.

For drug products in each category, FDA solicited a report from an advisory committee with respect to the conditions under which OTC drugs in that category are safe, effective, and not misbranded. FDA published each report as a "proposed monograph" in the Federal Register. All panels have concluded their work, and every panel report has been published. Publication triggered a public comment period. After review of the comments submitted, FDA published a "tentative final monograph" (TFM), allowed further comment, and scheduled an oral hearing if

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<sup>10</sup> 76 Stat. 780 (1962).

reasonable grounds existed for a hearing. A tentative final monograph has been issued in virtually every rulemaking.

The OTC Drug Review regulations allow only a limited period of comment after publication of a TFM: "Within 12 months after publishing a [TFM], any interested person may file . . . new data and information to support a condition excluded from the monograph in the tentative order."<sup>11</sup> However, "New data and information submitted after the time specified in this paragraph but prior to the establishment of a final monograph will be considered as a petition to amend the monograph and will be considered by the Commissioner only after a final monograph has been published in the Federal Register."<sup>12</sup> The FDA may make an exception if it "finds that good cause has been shown that warrants earlier consideration."<sup>13</sup>

Although virtually every TFM has been published, final monographs have been issued in only two-thirds of the therapeutic categories. Final monographs have not been issued in the following rulemakings: anti-diarrheal drug products, antimicrobial/antiseptic (first aid) drug products, antimicrobial/health care drug products, antimicrobial/mercurial drug products, antiperspirants, cough/cold combination drug products, oral health care (antimicrobial) drug products, oral health care (other), oral discomfort (relief) drug products, overindulgence remedies, poison treatment products, skin bleaching agents, skin protectants - fever blister/cold sore drug products, and vaginal

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<sup>11</sup> 21 C.F.R. 330.10(a)(7)(iii).

<sup>12</sup> 21 C.F.R. 330.10(a)(7)(v).

<sup>13</sup> Id.

contraceptive products.<sup>14</sup> In each of these rulemakings, a tentative final monograph has been issued and the twelve-month period for supplementing the administrative record has expired.

Manufacturers of OTC drug products have turned to the citizen petition process as a means of alerting the agency to data developed during the years that can elapse between publication of a TFM and publication of the final rule. Typically a manufacturer will file a citizen petition requesting that the agency reopen the administrative record in the proceeding. Some also, or instead, request that the agency modify the TFM.

Many instances can be cited where the administrative record in a monograph proceeding has been reopened, in response to a citizen petition, in order to allow the introduction of new data. These include:

- OTC Laxative Drug Products. In response to citizen petitions filed on January 8, 1991, by CIBA Consumer Pharmaceuticals, and on July 10, 1991, by Purdue Frederick Company, FDA reopened the administrative record after the TFM on OTC laxative drug products was published in 1985, to include data about the stimulant laxative active ingredient derived from senna and about psyllium-bran combination drug products.<sup>15</sup>

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<sup>14</sup> HPA, Tentative and Final Monograph Listing, <[www.chpa-info.org/issues/issuesTentative.html](http://www.chpa-info.org/issues/issuesTentative.html)> (visited February 15, 2000).

<sup>15</sup> 50 Fed. Reg. 2124 (January 15, 1985) (tentative final monograph); 57 Fed. Reg. 23174 (June 2, 1992) (reopening administrative record).

- OTC Anticaries Drug Products. In response to a citizen petition filed on November 15, 1989, by the Colgate-Palmolive Company, FDA reopened the administrative record after the TFM on OTC anticaries drug products was published in 1985, to include data and information supporting a 350-mg total fluorine dentifrice package size.<sup>16</sup>
- OTC Skin Protectant Drug Products. In response to a citizen petition filed on December 21, 1990 by Hüls America Inc., FDA reopened the administrative record after the publication in 1983 of the TFM governing OTC skin protectant drug products, in order to consider hard fat.<sup>17</sup>

Instances can be cited where FDA has not only accepted new data but also directly amended the TFM in question. Examples include:

- OTC Sunscreen Products. In response to a citizen petition filed on March 3, 1993, by Givaudan-Roure Corporation, FDA reopened the administrative record in the sunscreen products category to consider the monograph status of avobenzone for UVA protection, and then amended its proposed rule.<sup>18</sup>
- External Analgesic Products. In response to a citizen petition filed on May 28, 1987, by the Upjohn Company, FDA amended the 1983 tentative final monograph governing external analgesic products, to propose OTC status to hydrocortisone at a concentration above 0.5 percent up to 1 percent and hydrocortisone acetate equivalent to above 0.5 percent up to 1 percent hydrocortisone.<sup>19</sup>

In addition, some final monographs reflect data introduced by citizen petition more than twelve months after publication of the TFM. For instance:

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<sup>16</sup> 50 Fed. Reg. 39854 (Sept. 30, 1985) (tentative final monograph); 57 Fed. Reg. 19823 (May 8, 1992) (reopening administrative record).

<sup>17</sup> 48 Fed. Reg. 6820 (February 15, 1983) (tentative final monograph); 56 Fed. Reg. 65873 (December 19, 1991) (reopening administrative record).

<sup>18</sup> 58 Fed. Reg. 28194 (May 12, 1993) (tentative final monograph); 61 Fed. Reg. 48645 (September 16, 1996) (proposed amendment); 62 Fed. Reg. 23350 (April 30, 1997) (statement of enforcement policy).

<sup>19</sup> 48 Fed. Reg. 5852 (Feb. 8, 1983) (tentative final monograph); 55 Fed. Reg. 6932 (February 27, 1990) (proposed amendment).

- Internal Analgesic, Antipyretic, and Antirheumatic Drug Products. In response to a citizen petition filed on April 13, 1992, by the Aspirin Foundation of America, FDA amended the 1988 TFM on Internal Analgesic, Antipyretic, and Antirheumatic Drug Products to include in the professional labeling of aspirin an indication for suspected acute myocardial infarction. The final monograph has since been issued, with this new indication in the labeling.<sup>20</sup>

These are illustrative, but not exhaustive, examples of the extensive use of citizen petitions as part of the OTC Drug Review process. The point is this: years can elapse between the publication of a tentative final monograph and publication of a final monograph. Both the OTC drug industry and FDA have found the citizen petition process to be an appropriate and useful mechanism for ensuring that the final monograph -- when issued -- reflects current information on effective conditions of marketing.

## **2. The Proposed Regulations Can Be Read to Preclude the Process Whereby this New Information is Introduced.**

The proposed regulations appear to preclude further use of the citizen petition process in the OTC Drug Review. As noted, the proposed regulations would permit only citizen petitions that (a) pertain to an already-issued order; (b) request the issuance, amendment, or repeal of a regulation; or (c) are authorized by another FDA regulation. The petitions relied on by industry and FDA in the OTC Drug Review appear not to fall with any of these categories.

First, such a petition does not appear to request the issuance, amendment, or repeal of a regulation. While a court might find a TFM to be tantamount to a "regulation," FDA has not itself stated that it views TFMs as regulations for purposes of

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<sup>20</sup> 53 Fed. Reg. 46204 (November 16, 1988) (tentative final monograph); 61 Fed. Reg. 30002 (June 13, 1996) (proposed amendment); 63 Fed. Reg. 56802 (October 23, 1998) (final monograph for proposed amendment only).

proposed Sections 10.25 and 10.30.<sup>21</sup> Even if FDA were to do so, under the proposal it could still reject a petition styled as a request to reopen the administrative record.

Second, no regulation authorizes petitions to reopen the administrative record in the OTC Drug Review. While section 330.10(a)(7)(v) gives the Commissioner discretion to reopen the administrative record of an OTC monograph if "good cause" exists, it does not explicitly authorize citizen petitions. FDA has not indicated that it construes Section 330.10(a)(7)(v) as a regulation "authorizing" citizen petitions within the meaning of the proposed Section 10.25.

Third, neither a citizen petition requesting that the agency reopen the administrative record in a monograph proceeding, nor a petition or amend the TFM, pertains to an already-issued "order."

### **3. The Agency Should Remedy This Oversight.**

The agency surely did not intend to propose regulations that would preclude citizen petitions to reopen the administrative record in an OTC drug monograph proceeding. The large number of times the agency has granted such petitions indicates the agency recognizes the value and appropriateness of this procedure.

Such petitions have nothing in common with the concerns that prompted the proposed rule. In the preamble, FDA discusses "frivolous" and "repetitive" petitions, petitions that request action beyond the agency's jurisdiction or that pertain to matters

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<sup>21</sup> In addition, if a TFM is a "rule" for purposes of the Administrative Procedure Act, 5 U.S.C. §§ 552 et seq., the agency would be required to accept any citizen petition to amend the TFM. See 5 U.S.C. § 553(e) (requiring an agency to give interested persons the right to petition for "the issuance, amendment, or repeal of a rule.").

requiring legislative relief, and petitions filed for "improper purposes."<sup>22</sup> The OTC Review petitions described supplement the record in a rulemaking when science has advanced before the agency has concluded its work. They do not add to the agency's workload, as the staff would be obliged to review the data in any event.

This oversight should be remedied. The agency should clarify that a petition to reopen the record in a monograph proceeding and a petition to amend a TFM will be treated as previously. Failure to do so would result in the issuance of instantly-obsolete monographs. It would also contravene the agency's stated goal of efficiency: by postponing its review of new data until after issuance of a final monograph, the agency would make each remaining decision in the OTC Drug Review twice. The proposal could also force new ingredients and claims out of the monograph process and into new drug applications -- a more time-consuming and resource-intensive process for both manufacturers and FDA.

**B. Under the Proposed Regulations, FDA Could Avoid Addressing the Merits of Petitions in the OTC Drug Review.**

Even if the agency clarified that a petition to reopen the administrative record or to amend the TFM in an OTC monograph proceeding will be permitted under the proposed regulations, CHPA opposes the proposal because it could allow the agency to avoid addressing these petitions on the merits.

First, the proposed regulations would allow FDA to treat as correspondence any petition that "involves issues that are the subject of an ongoing or

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<sup>22</sup> 64 Fed. Reg. at 66822.

future administrative proceeding."<sup>23</sup> FDA has not explained how it proposes to determine whether a particular topic will be addressed in the future. We are concerned that this provision might be used to justify ignoring petitions to reopen the administrative record in a monograph proceeding, as the data in question will almost certainly be submitted in the future if it is not accepted at the time of petitioning.

Second, under the proposed regulations, a citizen petition that relates to a pending proceeding at the agency would be referred to the docket of that proceeding and treated as comments.<sup>24</sup> FDA does not indicate whether it will waive any deadline for the submission of comments that might have already expired in that proceeding. This will have a direct impact on the OTC Drug Review, where petitions are filed precisely because the period for comments on a TFM has expired.

Third, under the proposed regulations, FDA would treat as correspondence any petition that "presents scientific or technical issues or data that are specific to a particular product or class of products."<sup>25</sup> As drafted, this would appear to include any petition requesting the agency reopen the administrative record in an OTC monograph proceeding, as well as any petition for amendment of a tentative final monograph.

Neither correspondence nor the other means of communication cited by the agency -- meetings, telephone calls, electronic mail, and facsimiles -- are an adequate substitute for the petitioning process. The agency did not perceive them as adequate in 1975, when it promulgated the citizen petition regulation. The thousands of parties who

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<sup>23</sup> 64 Fed. Reg. at 66828 (proposed Section 10.30(e)(4)(i)(A)).

<sup>24</sup> Id.

<sup>25</sup> 64 Fed. Reg. at 66828 (proposed Section 10.30(e)(4)(i)(B)).

have filed citizen petitions since 1975 apparently find these alternatives unsatisfactory. They do not guarantee FDA involvement at high levels within the agency. FDA can choose not to address the merits of the request, or, indeed not to respond at all. Any response that might issue is not binding on the agency, and the agency can argue that the decision is not "final" for purposes of judicial review.

Thus, as urged above, the agency should clarify that a petition to reopen the record in a monograph proceeding and a petition to amend a TFM will be treated as previously.

**C. The Proposed Regulations Would Allow the Agency to Avoid Addressing the Merits of Important Petitions Outside the OTC Drug Review.**

CHPA also opposes the proposed regulations because they would allow FDA to deny or treat as correspondence any petition that "does not involve a significant public health or consumer protection issue."<sup>26</sup> Many important issues raised in citizen petitions do not involve public health or consumer protection. Below are some that are important to the OTC industry.

Agency Practice and Procedure. Important issues pertaining to the agency's practices and procedures can be raised in a citizen petition. For instance, the Good Guidance Practice regulations<sup>27</sup> were the direct result of a citizen petition filed by the Indiana Medical Device Manufacturers Council, requesting that FDA exert greater control over the initiation, development, and issuance of guidance documents, in order to

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<sup>26</sup> 64 Fed. Reg. at 66828 (proposed Section 10.30(e)(4)(i)(D)).

<sup>27</sup> 62 Fed.Reg. 8961 (February 27, 1997).

ensure public participation in the process.<sup>28</sup> More recently, a law firm filed a citizen petition, questioning the fairness of the agency's practice of posting warning letters on its web site without subsequent follow-up.<sup>29</sup> Under the proposal, FDA could treat these as correspondence.

Burdens Associated With Hasty Implementation of Labeling Changes. A citizen petition can be used to draw the agency's attention to the economic impact of an effective date or compliance date for labeling changes. For instance, FDA postponed the effective date for a portion of the final rule concerning labeling of aspartame as an active ingredient in human drug products, in response to citizen petitions.<sup>30</sup> This petition could be treated as correspondence under the proposed rule.

These issues are important to the OTC drug industry, and to the larger public. They should be addressed in a public proceeding during which the agency willingly engages in dialogue with members of the public, and after which the agency is accountable in a court of law.

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<sup>28</sup> FDA Docket No. 95P-0110 (May 2, 1995).

<sup>29</sup> FDA Docket No. 99P-1656 (May 27, 1999).

<sup>30</sup> 52 Fed. Reg. 12152 (April 15, 1987).

### III. CONCLUSION

The citizen petition process is an important safeguard of access to the agency, whereby members of the public are able to raise issues of safety, health, and public policy, and are assured of the agency's attention. The proposal would eliminate this safeguard of access, and curtail important dialogue. For the reasons discussed above, CHPA opposes the proposed rule.

Respectfully submitted,

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