

# Procter & Gamble

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Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

## PETITION FOR STAY OF ACTION

The Procter & Gamble Company ("P&G") submits this petition to request that the Commissioner of Food and Drugs stay for six months the effective date of the final rule<sup>1</sup> requiring that labeling for over-the-counter ("OTC") nasal decongestant drug products change the name of the listed active ingredient l-desoxyephedrine to levmetamfetamine. Under the final rule, labeling must reflect this name change by July 30, 1999. P&G is requesting a six month extension of this date, because unforeseen interruption in its raw material supply has left the company unable to deplete the existing labeling stock for our Vicks Vapor Inhaler. With additional time, P&G will be able to exhaust the current label supply.

## DECISION INVOLVED

On July 30, 1998, the Food and Drug Administration ("FDA") published a final rule amending the final monograph for OTC nasal decongestant drug products and requiring that labeling change the name of the active ingredient "l-desoxyephedrine" to "levmetamfetamine." The name change reflects a new United States Pharmacopeia ("USP") monograph, which includes levmetamfetamine as the new name for what had formerly been l-desoxyephedrine. Although both FDA and the Drug Enforcement Administration ("DEA") objected to the name change, the USP

<sup>1</sup> 63 Fed. Reg. 40647 (July 30, 1998) (codified at 21 C.F.R. § 341.20)

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adopted the new name based on the recommendation of the United States Adopted Names Council and its interpretation of International Nomenclature Name policies. 63 Fed. Reg. at 40648. FDA has identified no public health concerns requiring the chemical name change.

In adopting the USP monograph and the name change, FDA provided for a one-year effective date, such that labeling must reflect the new established name by July 30, 1999. FDA set this effective date in order to allow manufacturers "sufficient time to incorporate the change during a future manufacturing cycle." 63 Fed. Reg. at 40649. As explained below, P&G has prepared and obtained new labeling; however, special circumstances have prevented P&G from using its old labeling during the one-year period in which FDA envisioned such labeling would be used up.<sup>2</sup>

#### ACTION REQUESTED

P&G requests that the FDA extend until January 30, 2000 the deadline for changing the name of ingredient l-desoxyephedrine to levmetamfetamine in the OTC nasal decongestant monograph. P&G files this petition for stay of action more than 30 days after FDA's publication of the final rule, and requests permission to file for good cause under 21 C.F.R. § 10.35 (b) & (g). The need for a stay now has only recently become apparent when P&G understood the extent and duration in the interruption of our raw material supply. The six month extension will allow P&G to exhaust its current supply of product labeling.

#### STATEMENT OF GROUNDS

**I. P&G has been unable to deplete its current labeling because of an unforeseen accident at the factory of its raw material supplier.**

FDA stated when it promulgated the final rule requiring the change from ingredient l-desoxyephedrine to levmetamfetamine that it was providing a one-year effective date in order to allow manufacturers to make the change during future manufacturing runs. 63 Fed. Reg. at 40649. P&G

moved promptly after publication of the rule to begin working on new labeling art and copy for our Vicks Vapor Inhaler. Unfortunately, the lone global supplier of the active ingredient, l-desoxyephedrine, suffered an explosion at its factory in August 1998 and halted all production.

Complicating this situation was the fact that this lone supplier was also in the process of selling their operation. P&G worked with the lone global supplier and its buyer to help them understand the situation even as the sale of the company was progressing. The sale was completed late December 1998. Although the new owner applied for a DEA license in early January, 1999, they did not have DEA approval to produce product until after the effective date of the final rule. They completed their first full production run in August 1999.

As a result, P&G has remained unable to manufacture finished product for months during the critical period leading up to the effective date of the final rule, July 30, 1999. Absent the explosion at our supplier's factory, P&G would have exhausted all our old labeling as part of our normal business cycle, just as the FDA envisioned when assessing the impact of the regulation. However, with the explosion, P&G is left with a substantial stock of old labeling. Currently, we are unable to use these old labels and they will become obsolete if P&G is not given additional time to exhaust the inventory as our normal production resumes.

**II. Good cause exists to grant the stay.**

Under 21 C.F.R. § 10.35(e), FDA shall grant a stay where: (1) the petitioner will suffer irreparable injury without the stay; (2) the petitioner's case is not frivolous and is brought in good faith; (3) the petitioner has demonstrated sound public policy grounds in support of the stay; (4) public health or other public interests do not outweigh the resulting delay. P&G satisfies each of these criteria.

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<sup>2</sup> In this respect, P&G is in a position similar to Leiner Health Products, who filed a Petition for Stay of Action on July 7, 1999.

**1. P&G will suffer irreparable injury without the stay.**

Without the stay P&G will suffer irreparable economic injury. Our inventory is worth approximately \$41,752. All of this labeling will have to be discarded if our petition is denied. P&G has no way to recoup this loss.

**2. P&G's petition is *bona fide* and pursued in good faith.**

P&G's petition is neither frivolous nor pursued in bad faith. P&G needs the extension of the effective date of FDA's final rule because of the unfortunate explosion at the factory of our raw material supplier. P&G began work on new labeling and copy but we were simply unable to use the existing labels we had on hand due to the shortage of raw material. P&G has only recently realized that the supply situation would not change before the July 30, 1999 deadline. Despite our good faith efforts with the original supplier, the DEA and the new supplier (buyer), raw material has not been made available to us until past the effective date of the final rule.

Although we have an existing inventory of new labels to ensure P&G complies with the new rule, we are pursuing this petition in order to eliminate the waste of \$41,752 worth of old labels. This waste would be particularly unjustified because the labeling change relates to a technical issue of chemical nomenclature and not a public health concern.

**3. Granting the stay would avoid economically wasteful actions and promote the objectives FDA sought to capture in its initial rule.**

Public policy supports the grant of stay. The FDA noted in promulgating the final rule that the costs of the rule involved were "not economically significant." 63 Fed. Reg. at 40649. This conclusion was based on a premise that "an effective date of 1 year . . . will provide manufactures sufficient time to incorporate the name change during a normal manufacturing cycle." *Id.* P&G's normal manufacturing cycle was crippled by the explosion at the manufacturing plant of our raw material supplier. Granting P&G additional time for complying with the required name change will

allow us sufficient time to complete a normal manufacturing cycle and will be consistent with FDA's own stated objective of allowing manufacturers sufficient time to incorporate the new labeling during a normal manufacturing cycle.

Adherence to the July 30, 1999 effective date will impose costs on P&G and other companies with no corresponding public benefit, while granting a stay will avoid costs with no public harm. Granting the stay promotes good regulatory policy in accordance with Executive Order 12,866 which directs agencies to "assess all costs and benefits of available regulatory alternatives" and "select those approaches that maximize net benefits."

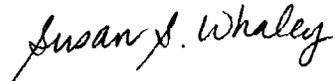
**4. No countervailing public health concern or other considerations require denial of P&G's stay request.**

No public health concern or other public interest considerations compel denial of the stay. Unlike other regulations, the final rule at issue here was driven by a technical issue of chemical nomenclature following the USP's adoption of a new monograph, and was not spurred by any pressing public health concern. Both FDA and DEA opposed the name change for fear that adoption of the name "levmetamfetamine" might encourage the diversion of legal drug products for use in the illicit manufacture of methamphetamine. 63 Fed. Reg. at 40648. The FDA identified no public health or public policy basis for its regulation other than the desire to track the new USP monograph. Accordingly, no public health risk is created by allowing P&G a limited additional period of time in which to deplete its old labeling, just as no risk was created by FDA's initial determination to allow companies to use the old labeling for one year following publication of the final monograph for OTC nasal decongestants.

**CONCLUSION**

For the foregoing reasons, the requested stay of action should be granted.

Respectfully submitted,



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