

CHATTEM

Charles N. Jolly
Vice President—Legal

January 26, 1979

EXECUTIVE SECRETARIAT			
Food and Drug Administration			
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Donald Kennedy, Ph.D.
Commissioner of Food and Drugs
Office of the Hearing Clerk
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Over-the-Counter Drugs: Proposed Establishment of
a Monograph for Skin Bleaching Drug Products for
Over-the-Counter Human Use, 43 Fed. Reg. 51546 et seq.
November 3, 1978, Docket No. 78N-0065

Dear Sir:

These comments are filed in quintuplicate, on behalf of Chattem, Inc. (hereinafter Chattem), a manufacturer and distributor of NADINOLA® brand OTC skin bleaching drug products for human use. Chattem is interested in and affected by this proposal.

1. Statement of Identity (Section 358.50, FR page 51554)
Chattem urges that the term "skin bleaching agent" not be designated as the approved statement of identity for hydroquinone-containing drug products. It is Chattem's belief based on years of experience and research in this area that the term "bleaching" is viewed by the consumer as inappropriate and inconsistent with their use of these products.

In general, consumers view a "bleach" as a harsher and more severe form of color alteration than is intended or is likely to be produced by the use of 2% hydroquinone products. The intention of the consumer is usually to make areas of blotchy skin more uniform. It is not used, in general, to cause the skin to become uniformly lighter in shade, which is the commonly perceived use of a "skin bleach."

The following quotes are illustrative of consumer use of terminology in this area:

A Chicago, Illinois, secretary: "I use it on the blotches and the blotches are darker and it makes the darkness go away, ... but I don't think of that as bleaching."

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A Chicago, Illinois, student: "I really feel that most people are more interested in smoothing the complexion than getting light. I don't care what color my skin is just so it is a nice, smooth skin."

A Chicago, Illinois, clerk: "The reason I use one (hydroquinone-containing skin toner) is to lighten the blackened areas; not to get light, but to lighten the dark areas."

We are unaware that the word "bleach" has any more precise medical significance than "skin toner" and, accordingly, would urge the Commissioner not designate the words "skin bleaching agent" as the appropriate statement of identity. Chattem would prefer the expression "skin toner."

2. Warnings (Section 358.50(c), FR page 51555)

Chattem objects strenuously to the warning appearing in Section 358.50(c)(1), particularly the requirement that the warning be conspicuously boxed and in red letters.

The panel apparently believes some form of highlighting is necessary for this particular warning if, in fact, the required terminology is a warning. Chattem feels that highlighting formats such as boxing should be reserved for only the most serious and urgent labeling information. It seems apparent that some quantification of the risk presented is necessary before one arbitrarily assigns a box warning to a statement. In no case short of "poison" labeling do we feel that red coloring should be specifically required. In the appropriate case special type face or bold print might well be methods by which truly significant warnings could be required to be highlighted in the monograph. In this case, we frankly question whether the language communicates information of such seriousness as to deserve highlighting. Specification of a particular required color is both unjustified and unsupported by panel findings.

There is a further inconsistency in that the proposed warning fails to differentiate between single ingredient hydroquinone products and hydroquinone combined with sunscreen agents, which are provided for elsewhere under the proposed monograph (see 358.20). Combination products meeting Section 358.20 requirements would, by definition, satisfy by their very formulations the question of concurrent use a sun blocking agent which is at the heart of the proposed warning.

Chatterm urges that the requirement of a box warning be dropped in its entirety, or if retained, modified substantially to confine the warning to the use of appropriate type size, and style and then only to products not already containing an approved sunscreen in combination.

3. Patch Testing (See FR page 51550)

Chatterm notes that the text of the panel report suggests that "the use of hydroquinone for depigmenting ... should never be considered without a cautious therapeutic trial on a limited, inconspicuous area." These remarks were largely in the context of remarks supporting the safe use of hydroquinone in 2% and 3% concentrations, noting some risk in concentrations of 5% or higher. Accordingly, the absence of a specific patch testing section in the proscribed labeling is interpreted as indicating that hydroquinone preparations containing between 1.5% and 2% concentrations do not present sufficient risk of sensitivity reactions to justify patch testing labeling. Chatterm urges that the Commissioner resolve any outstanding uncertainty by making an express finding in the tentative final order that patch testing labeling is not required under the monograph.

4. Category II Labeling (FR page 51553)

The panel would prescribe a number of quite useful expressions used commonly by consumers in describing the conditions for which they find hydroquinone containing products useful. Inasmuch as the industry was at no time required to submit data establishing consumer terminology appropriate to the Category, other than actual labeling claims, Chatterm urges that the panel conclusion that terms such as "skin discolorations," "hand spots," "blotches," and "blotchy skin" are "poorly defined" is improper. Even were the panel qualified to receive testimony on semantic questions (which it is not), no call for submissions was made by the agency for such information. The monograph should be revised to indicate that any of these or other similar terms may be used under appropriate circumstances not inconsistent with the use of approved indications.

The panel also seems to go out of its way to address certain cosmetic claims made for cosmetic/drug products subject to the monograph. Chatterm believes that the panel is without a proper jurisdictional basis for passing on the accuracy of wholly cosmetic claims. The criteria applied by the panel in the review, i.e., safety and efficacy as demonstrated by published literature and clinical studies, is not in all

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Page Four

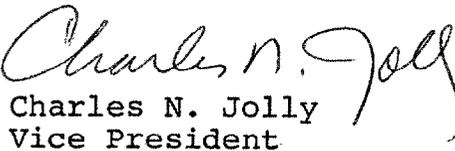
respects the appropriate standard for cosmetic claims. The tentative final monograph should make clear that the monograph is directed to the drug ingredients and claims relating of these drug/cosmetic products and specifically does not preclude wholly cosmetic claims not inconsistent with approved indications.

5. Other Matters

Chattem notes with approval and adopts by reference the comments of the Proprietary Association, especially those remarks concerning as the Legal Status of the Monograph; Labeling: Indications for Use; Specific Indications for Use; Warning Statements for Combination Products; Directions; and Permitted Combinations are concerned.

Chattem urges that the Commissioner modify the proposed monograph as indicated above prior to republication of the proposal as a tentative final order.

Sincerely,


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CNJ/lpb



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Page Four

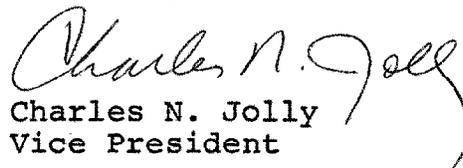
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