At this time, a group of doctors called together by the Food and Drug Administration believe it is okay to continue to use benzoyl peroxide to help clear up pimples while more studies are being done. There is no evidence that the drug causes tumors or causes tumors to grow faster in humans.

If you decide to use this medicine, you should try to avoid possible causes of tumors. Because sunlight can cause tumors in humans, you should stay out of sunlight as much as possible and use a sunscreen when you go outside.

This leaflet will be revised when more is known about the effects of benzoyl peroxide.

This labeling would apply equally to both OTC and rescription drug products that contain benzoyl peroxide. At this time, only one prescription product (a combination product containing benzoyl peroxide and erythromycin) is subject to an approved application. Other prescription products are currently marketed without approved applications. This labeling would apply to any prescription product containing benzoyl peroxide, whether marketed under or without an approved application.

The agency is especially concerned whether the benzoyl peroxide warning will be read and understood by teenagers, the largest group of targeted consumers of acne drug products, and, if read, if they will comply with the warning. An additional concern is the possibility that the proposed labeling may result in teenagers not treating acne at all, although dermatologists consider this an abnormal skin condition that should be treated. Based on these concerns, the agency invites public comment, particularly with supporting information, regarding label reading, label understanding, and making use of the information, especially with regard to the teenage population. The agency also invites comment on whether the proposed consumer package insert would provide useful information to teenagers. An alternative to the labeling approach that FDA is proposing would be to place the ingredient on prescription status until the testing is completed. At that time, the skin tumor promotion issue and the effects of sun exposure should be resolved, and a final decision can be made on the monograph or nonmonograph status of this ingredient.

Based on all information currently available, the agency considers the known benefits of the OTC availability of products containing benzoyl peroxide to exceed the possible safety risks. However, until a final determination is made on the OTC status of benzoyl peroxide, the agency tentatively concludes that additional information about the ingredient needs to be provided to consumers. The agency considers the labeling being proposed in this document to be in accord with the provisions of sections 201(n) and 502(a) of the act (21 U.S.C. 321(n) and 352(a)).

The agency acknowledges that there currently is a lack of information on possible interactions between products containing benzoyl peroxide and products containing a sunscreen (or sunscreens). There are numerous benzoyl peroxide products in the marketplace, and these products are formulated with a variety of inactive ingredients. Likewise, there are many sunscreens in the marketplace, and these products are formulated with a variety of inactive ingredients, which in some cases are different than those contained in the benzoyl peroxide products. However, the agency is unable to state whether any incompatibilities may occur when the two types of products are used sequentially. The agency believes that users should allow the benzoyl peroxide to dry before applying the sunscreen. This would not be a concern if the benzoyl peroxide is applied at bed time and the sunscreen is applied the following morning. However, some users will reapply the benzoyl peroxide in the morning before going outside. Sunscreen applied soon after the benzoyl peroxide could interact with the benzoyl peroxide product. Therefore, the agency is considering the following product labeling to inform consumers: ''There currently is a lack of information on possible interactions between products containing benzoyl peroxide and products containing a sunscreen (or sunscreens).''

The agency is aware that the prescription ingredient tretinoin, which is used for the topical treatment of acne, states in its labeling (Ref. 17) that ''Use of sunscreen products and protective clothing over treated areas is recommended when exposure [to sunlight] cannot be avoided.'' However, the labeling does not provide any directions about the time or method of applying he sunscreen. The same manufacturer also markets benzoyl peroxide acne drug products. Thus, the manufacturer may have information in its files about the use of a sunscreen following topical acne drug products containing benzoyl peroxide. Manufacturers of both benzoyl peroxide and sunscreen products are invited to comment on the appropriateness of a waiting period between application of the two products and to submit any information available in their files on sequential use of these types of products.

Because the agency is encouraging manufacturers of benzoyl peroxide products to voluntarily implement the labeling in this proposal as soon as possible (see discussion below), manufacturers may wish or need to add additional information in their labeling about application intervals as appropriate for their specific product.

References

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(3) Comment No. RPT, Docket No. 81N–0114, Dockets Management Branch.

(4) Comment No. RPT 00002, Docket No. 81N–0114, Dockets Management Branch.

(5) Comment No. SUP00002, Docket No. 81N–0114, Dockets Management Branch.

(6) Comment No. SUP00003, Docket No. 81N–0114, Dockets Management Branch.

(7) Comments No. C31, PR1, and PR2, Docket No. 81N–0114, Dockets Management Branch.

(8) Transcript of 34th meeting of FDA's Dermatologic Drugs Advisory Committee, April 10, 1992, Bethesda, MD, pp. 10–22, 112–117, 146–149, 177–184, 234–236, and 262–266, OTC vol. No. 07BP, Docket No. 92N–0311, Dockets Management Branch.

(9) Comment No. MM4, Docket No. 81N–0114, Dockets Management Branch.

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(13) Comment No. C6, Docket No. 81N–114A, Dockets Management Branch.

(14) Comment No. C7, Docket No. 81N–114A, Dockets Management Branch.

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(16) Hogan, D. J. et al., ''A Study of Acne treatments as Risk Factors for Skin Cancer of the Head and Neck,'' *British Journal of Dermatology*, 125(4):343–348, 1991.

(17) ''Physicians Desk Reference—1993,'' 47 ed., Medical Economics Co., Montvale, NJ, pp. 1736–1737, 1993.

Manufacturers of all drug products containing benzoyl peroxide are