DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 92N-0311]

Topical Drug Products Containing Benzoyl Peroxide; Required Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing additional labeling (warning and directions) for all topically-applied acne treatment drug products containing benzoyl peroxide. The warning advises consumers to avoid unnecessary sun exposure and to use a sunscreen when using a benzoyl peroxide product to treat acne. The directions provide information about applying benzoyl peroxide and a sunscreen, and about discontinuing use of both products if irritation or sensitivity develops. Prescription drug products will need a patient package insert to convey this information to product users. The agency is requesting public comment on whether a consumer package insert should be required to provide additional information FDA believes users of these benzoyl peroxide products should have. That information would summarize some problems that occurred when benzoyl peroxide was used in tests on mice and would mention that additional studies are currently being conducted. The final status of benzoyl peroxide in over-the-counter (OTC) drug products and the continued need for the additional labeling will be determined when these additional studies are completed and evaluated.

DATES: Written comments on the proposed regulation by May 18, 1995. Written comments on the agency's economic impact determination by May 18, 1995. FDA is proposing that the final rule based on this proposal be effective 6 months after the date of its publication in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 7, 1991 (56 FR 37622), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an amendment of the tentative final monograph for topical acne drug products for OTC human use in which the agency reclassified benzoyl peroxide from its previously proposed monograph status (Category I) to "more-data-needed" (Category III) status. This action (56 FR 37622) was based on new information that raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice (Ref. 1) and a study that reported that benzoyl peroxide has tumor initiation potential (Ref. 2).

Subsequently, a drug manufacturers association submitted data and information in support of the safety of benzoyl peroxide (Refs. 3 through 6). FDA evaluated these data and information and determined that the studies show that benzoyl peroxide is a skin tumor promoter in more than one strain of mice as well as in hamsters. To date, topical studies (which have shown only tumor promotion) have been of short duration (about 52 weeks). Although animal data and human epidemiology data are available, the agency has determined that further studies are necessary to adequately assess the tumorigenic potential of benzoyl peroxide. These studies are currently being conducted (Ref. 7). The agency acknowledges that it may take several years for these studies to be completed and analyzed, and for a final determination to be made on benzoyl peroxide's safety.

Because studies have shown that benzoyl peroxide is a skin tumor promoter in animals, and the relevance of this finding to humans is unknown, the agency was concerned about continued OTC marketing during the several years it will take to resolve the safety issues raised by the studies discussed above. Because of this concern, the agency discussed this matter with its Dermatologic Drugs Advisory Committee (the Committee) on April 10, 1992 (Ref. 8). At that meeting, information was presented by representatives of FDA and industry, consumer, and professional organizations. The Committee was asked to assess the safety and efficacy data available for benzoyl peroxide, to consider the benefit-to-risk ratio, and to recommend whether the product should continue to be available for use while further safety data are developed. The Committee voted unanimously that benzoyl peroxide should remain available as an OTC drug product.

The Committee was also asked whether the OTC labeling of benzoyl peroxide drug products should be changed to include a statement concerning the ingredient's potential to cause skin tumors in animals, what is the relevance of this potential in humans, and how such a statement should be worded for consumers. The Committee recommended by a four to three vote (with one abstention) that information about what is known about benzoyl peroxide should be provided to consumers by some mechanism. Because of the lack of data, however, the Committee recommended that no warning statement concerning cancer should be included in the labeling of benzoyl peroxide products. The Committee recommended unanimously that FDA consider appropriate wording for additional labeling to highlight those areas where there may be risks and that the proposed wording be brought back to the Committee for review.

The Committee was also informed that the agency had previously recommended to industry that a lifetime animal carcinogenicity study to assess benzoyl peroxide's safety include, as part of the protocol, periods of exposure to UV light (Ref. 9). The Committee was asked its opinion on the need for such testing. Industry representatives stated to the Committee that studies already conducted by Iversen (Refs. 10 and 11) showed no evidence that benzoyl peroxide enhanced the carcinogenicity of UV light. After a lengthy discussion, the Committee concluded that the Iversen studies were insufficient to fully resolve this issue because they were not animal lifetime studies and an insufficient number of animals had been used. Further, based on the protocol, it was uncertain that the studies provided assurance that benzoyl peroxide's tumor fostering potential was conclusively assessed. The Committee recommended unanimously that a new photocarcinogenicity study should be conducted (Ref. 12). As noted above, this study is being conducted (Ref. 7).

A comment submitted after the Committee meeting (Ref. 13) from a consumer association urged the agency to move quickly to inform the American public of the possible health and safety risks associated with benzoyl peroxide. The comment did not recommend removal of this drug from the OTC market, but suggested several labeling statements that could be used. Another comment by a national manufacturers association (Ref. 14) suggested that FDA use alternative available methods, rather than labeling, to disseminate information on this subject. The association proposed: (1) Fact Sheets mailed to consumer groups and publishers of medical- and pharmacy-

related information, (2) publications in FDA Consumer, and (3) other similar and related mechanisms. The association stated that the OTC label should be maintained as an instructional tool for safe product use rather than for the dissemination of ambiguous, potentially frightening information that the consumer has little ability to make an informed decision about.

The association contended that labeling already proposed by the agency for benzoyl peroxide pertaining to "skin irritation" (50 FR 2172 at 2181, January 15, 1985) would take into account the hypothetical mechanism of skin tumor promotion which—although not known to occur in humans—represents the best model to date to describe the possible risk that is at issue with benzoyl peroxide. The comment concluded that the proposed warning conforms to the Committee's recommendations, i.e., avoids the term "cancer" yet provides information to the public, is instructional and actionable, and allows consumers to take definitive risk avoidance action by not using the product.

The agency has carefully considered the Committee's and the comments' views. The agency agrees that marketing of benzoyl peroxide should continue while the ongoing studies are being completed. The agency agrees that information should be provided to consumers and that no warning statement concerning cancer should be included in the labeling of benzoyl peroxide drug products because currently available data are inconclusive. The agency has given extensive consideration to the potential risks established to date, e.g., sun exposure, and is proposing certain labeling information that it believes should be provided to consumers now. The bases for these proposals follow

Although the skin tumor promotion caused by benzoyl peroxide in mice and hamsters is disturbing, the overall test results are not conclusive, and the risk to humans is unknown. In recent epidemiologic studies (Refs. 15 and 16), Hogan et al. concluded that there is no indication that the normal use of benzoyl peroxide in the treatment of acne is associated with an increased risk of acial skin cancer.

Benzoyl peroxide is a widely used and effective ingredient in the topical treatment of acne. As noted above, the Committee recommended unanimously that benzoyl peroxide should remain available as an OTC drug product while the additional studies to answer the unresolved safety questions are being conducted. When those studies are completed, the monograph or nonmonograph status of benzoyl peroxide will be resolved.

FDA has determined that the results of available animal studies do not provide a sufficient basis to restrict OTC marketing of benzoyl peroxide products at this time. However, the agency has tentatively determined that consumers who choose to use products containing this ingredient need to be informed about an additional condition related to this use, i.e., to avoid unnecessary sun exposure and to use a sunscreen. The agency has also determined that it would be desirable to provide users of benzoyl peroxide products some additional information about this drug based on the studies that have been and are being conducted.

The agency has considered the comments' viewpoints on how consumers should be informed about this new information and finds that the various suggestions have merit. The agency tentatively finds that the best way to directly inform users of benzoyl peroxide drug products about sun exposure and this ingredient is to provide the information in product labeling. The agency will also disseminate this information in other standard ways, e.g., the FDA Consumer and the FDA Medical Bulletin. The agency will be able to provide more detailed information in these publications than can be provided in OTC drug product labeling.

Based on the above discussion, the agency is proposing to require that the labeling of products containing benzoyl peroxide include a new warning and additional directions. The warning advises users of these products to avoid unnecessary sun exposure and to use a sunscreen. The agency believes that the warning information is important enough that it should appear in boldface type as the first statement under the heading "WARNINGS." The additional directions provide information about applying the benzoyl peroxide and sunscreen. For OTC drug products containing benzoyl peroxide, the agency is proposing that the following information be used:

(1) The following statement shall appear in boldface type as the first sentence under the heading "Warnings": "When using this product, avoid unnecessary sun exposure and use a sunscreen."

(2) The following information shall appear in the "Directions" section of the labeling: "If going outside, use a sunscreen. (sentence in boldface type) Allow [insert name of benzoyl peroxide product] to dry, then follow directions in the sunscreen labeling. If irritation or sensitivity develops, discontinue use of both products and consult a doctor."

Prescription drug products will need a patient package insert to convey this information to users of the product. For prescription drug products, the agency is proposing that this same information appear in a patient package insert in accord with 21 CFR 201.57(f)(2) and new § 201.318 (21 CFR 201.318) of this chapter, which is being proposed in this document.

The agency would like public comment on how beneficial it would be to provide users of OTC and prescription drug products containing benzoyl peroxide additional information on what is known about the ingredient. This information would summarize in lay language some problems that occurred when benzoyl peroxide was used in tests in mice and would inform users of the product that additional studies are currently being conducted. The information would also state that consumers can continue to use benzoyl peroxide products while these tests are being done. The agency is contemplating requiring this information to appear in a consumer package insert because it is too extensive to appear on the immediate container or carton labeling. If implemented, the requirement would appear as follows:

The following information shall appear in a package insert under the heading "Additional Information About" (insert brand name of benzoyl peroxide product):

What is in (insert brand name of benzoyl peroxide product)?

The main active ingredient in (insert brand name of product) is benzoyl peroxide. People have used it for more than 25 years to treat pimples and acne. In animal tests, benzoyl peroxide was put on the skin of mice after other chemicals known to cause tumors. Benzoyl peroxide appeared to make the tumors caused by the other chemicals grow faster, but benzoyl peroxide did not cause tumors by itself. Substances that cause tumors to grow or to grow faster in animals raise questions about the possibility of a similar effect in humans. However, many such substances have had no effect on human tumors.

Does Benzoyl Peroxide Cause Tumors to Grow in Humans?

A Canadian survey looked at people who did and did not use benzoyl peroxide. The people who used benzoyl peroxide did not have any more skin tumors than those who did not use it.

No one study can answer all the important questions about the effects of a medicine. This Canadian survey did not consider the effects of using benzoyl peroxide for many years or in places where people may be exposed to other causes of skin tumors, such as locations that get more sunlight. More studies are being done now.

What Should I Do?

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

(1) Slaga, T. J. et al., "Skin-Tumor Activity of Benzoyl Peroxide, A Widely Used Free Radical-Generating Compound," *Science*, 213:1023–1025, 1981.

(2) Kurokawa, Y. et al., "Studies on the Promoting and Complete Carcinogenic Activities of Some Oxidizing Chemicals in Skin Carcinogenesis," *Cancer Letters*, 24:299–304, 1984.

(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.

(10) Iversen, O. H., "Carcinogenesis Studies with Benzoyl Peroxide (Panoxyl gel 5%)," *Journal of Investigative Dermatology*, 86:442–448, 1986.

(11) Iversen, O. H., "Skin tumorigenesis and carcinogenesis studies with 7, 12-dimethylbenz [a] anthracene, ultraviolet light, benzoyl peroxide (Panoxyl gel 5%) and ointment gel," *Carcinogenesis*, 9:803–809, 1988.

(12) Transcript of 34th meeting of FDA's Dermatologic Drugs Advisory Committee, April 10, 1992, Bethesda, MD, pp. 277–279, OTC vol. No. 07BP, Docket No. 92N–0311, Dockets Management Branch.

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

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

(15) Hogan, D. J., T. To, and E. R. Wilson, "Drug and Non-Drug Risk Factors Associated With Facial Skin Cancer," A report to the Nonprescription Drug Manufacturers Association/the Nonprescription Drug Manufacturers Association of Canada on the Saskatchewan Study, Comment No. 4, Docket No. 81N–114A, Dockets Management Branch.

(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

encouraged to voluntarily implement this labeling as of the date of publication of this proposal, subject to the possibility that FDA may change the wording of the statement, or not require the statement, as a result of comments filed in response to this proposal. Because FDA is encouraging that the proposed labeling statement be used on a voluntary basis at this time the agency advises that manufacturers will be given ample time after publication of a final rule to use up any labeling implemented in conformance with this proposal.

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule is estimated to generate a one-time label modification, the cost of which will not be significant. Similarly, the costs incurred by small businesses are estimated to be insufficient to warrant a regulatory flexibility analysis. FDA believes that small marketers use relatively simple and inexpensive packaging and labeling. Hence, labeling change costs to small firms are not expected to be substantial. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on manufacturers of drug products that contain benzoyl peroxide. Comments regarding the impact of this rulemaking on benzoyl peroxide containing drug products should be accompanied by appropriate documentation. A period of 90 days from the date of pubication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before May 18, 1995, submit written comments to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before May 18, 1995. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507,508, 510, 512, 530–542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg-360ss, 371, 374, 379e); secs. 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

2. New § 201.318 is added to subpart G to read as follows:

§ 201.318 Labeling for benzoyl peroxide-containing topical preparations; required statements.

(a) Studies have shown that skin tumors were fostered in laboratory animals exposed to benzoyl peroxide and tumor initiators. It is also known that excessive sunlight can cause skin cancer in humans. Animal studies are in progress to investigate whether benzoyl peroxide is a tumor promoter or initiator in the absence and/or presence of sunlight. While these studies are being conducted, and until the results of the studies have been assessed, FDA concludes that the labeling of topical drug products containing benzoyl peroxide should inform users of the product that some harm may result from exposure to sunlight in conjunction with the use of products containing benzoyl peroxide. Accordingly, a warning and additional directions must appear in the labeling of prescription or over-the-counter (OTC) drug products that contain benzoyl peroxide.

(b) Any OTC drug product containing benzoyl peroxide for topical administration shall bear the following statement in its labeling:

(1) The following statement shall appear in boldface type as the first sentence under the heading "Warnings": "When using this product, avoid unnecessary sun exposure and use a sunscreen."

(2) The following information shall appear in the "Directions" section of the labeling: "If going outside, use a sunscreen. (sentence in boldface type) Allow [insert name of benzoyl peroxide product] to dry, then follow directions in the sunscreen labeling. If irritation or sensitivity develops, discontinue use of both products and consult a doctor."

(c) Requirement for a patient package insert for any prescription drug product containing benzoyl peroxide for topical administration. Each topical benzoyl peroxide product restricted to prescription distribution, including any benzoyl peroxide in fixed combination with other drugs, shall be dispensed to patients with a patient package insert containing the information in paragraph (c)(2)(iii) of this section. This requirement applies to any topical benzoyl peroxide drug product that is the subject of a new drug application approved either before or after October 9, 1962, and all identical, related, or similar drug products as defined in § 310.6 of this chapter, whether or not the subject of an approved new drug application.

(1) *Distribution requirements.* For topical benzoyl peroxide drug products, the manufacturer and distributor shall provide a patient package insert in or with each package of the drug product that the manufacturer or distributor intends to be dispensed to a patient. The patient labeling shall be provided as a separate printed leaflet independent of any additional materials provided with the product.

(2) *Patient package insert contents.* A patient package insert for a topical benzoyl peroxide drug product is required to contain the following information:

(i) The name of the drug.

(ii) The name and place of business of the manufacturer, packer, or distributor.

(iii) The following statement: WARNING: "When using this product, avoid unnecessary sun exposure and use a sunscreen." (sentence and word WARNING in boldface type)

(iv) The following information shall appear in the "Directions" section of the labeling: "If going outside, use a sunscreen. (sentence in boldface type) Allow [insert name of benzoyl peroxide product] to dry, then follow directions in the sunscreen labeling. If irritation or sensitivity develops, discontinue use of both products and consult a doctor."

(v) The date, identified as such, of the most recent revision of the patient package insert.

(3) *Requirements to supplement approved application.* Holders of approved applications for topical benzoyl peroxide drug products that are subject to the requirements of this section must submit supplements under § 314.70(c) of this chapter to provide for the labeling required by paragraph (c) of this section. Such labeling may be put into use without advance approval of the Food and Drug Administration provided it includes only the information included in paragraph(c) of this section.

(d) Any drug product subject to this section that is not labeled as required and that is initially introduced or initially delivered for introduction into interstate commerce after (insert date 6 months after date of publication of the final rule in the **Federal Register**) is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is subject to regulatory action.

Dated: January 31, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy

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