GOVERNMENT

FDA interpretation of advertising controls leads drug industry to withdraw objections to all but two proposals

AGREEMENT. Almost before FDA hearing examiner William E. Brennan opened the hearings, the drug industry representatives agreed to modifications of FDA rules controlling drug advertising

Industry Accepts Most FDA Rules on Drug Ads

Most of the issues between the drug industry and the Food and Drug Administration on new rules controlling drug advertising have been settled. When the regulations were first issued, the Pharmaceutical Manufacturers Association and 44 individual drug manufacturers filed a strong protest with FDA charging that the rules would disrupt normal drug advertising practices (C&EN, July 29, page 23). However, public hearings called to give industry a chance to air its views were adjourned immediately after the opening ceremonies when the drug makers withdrew their objections.

Industry withdrew its objections after FDA agreed to modify some of the language in the regulations and FDA Commissioner George Larrick wrote a letter to the objectors explaining how FDA would interpret the rules in various cases. As Gerhard A. Gesell, counsel for the 44 drug firms, put it at the hearings, "In view of the modified language and Mr. Larrick's letter, we withdraw our objections to all the regulations except one; no further hearings are required."

Still at issue is a regulation that would restrict advertising claims on drugs that have been in use for many years. And the rule dealing with the use of generic names on drug labels is the subject of a court suit (C&EN, Sept. 16, page 39).

Issues. Most of the drug industry opposition centered on two regulations. One called for a balanced presentation between side effects and contraindications and therapeutic claims in a drug advertisement; the other required prior approval of advertising by FDA in certain cases.

According to the drug industry, the regulation requiring a fair balance between a drug's advantages and disadvantages would give FDA the right to dictate layout, composition, and manner of drafting the entire text of advertisements. This would require information on side effects and contraindications to be given equal prominence in headlines or text with information on effectiveness. On this basis, side effects and contraindications would be overemphasized and could mislead physicians about the true usefulness of a drug, they said.

However, Commissioner Larrick made it clear that FDA does not intend to make sweeping changes in advertising techniques. "Our regulations are not intended to prohibit use of graphic presentations, headlines, or similar advertising techniques. Our basic purpose is to provide assurance that the advertisement will fairly present the message to the physician of what the drug will do, what its limitations are, and what side effects and contraindications may attend its use," he says.

Drug makers also protested the regulation which required prior FDA approval of advertisements for dangerous drugs if information on the dangers is of recent origin or has not been widely publicized in the medical literature. They argued that this rule, if strictly interpreted, could lead to virtual censorship of drug advertising by FDA. In their opinion, advertising for nearly all newly approved prescription drugs would have to be cleared in advance because information on them would be "of recent origin and not widely publicized."

FDA has agreed to relax this provision. Preclearance of advertising will be required only in "extraordinary cases." In these cases the company will be given an opportunity to develop a plan to warn physicians, such as inserting additional warning statements in subsequent advertising. If FDA judges the plan to be adequate, then the entire advertisement will not have to be submitted for approval.

JFK Sets Patent Policy For Federal Agencies

To promote greater consistency among government agencies in handling patents resulting from research and development projects, President Kennedy has issued a set of guidelines to control agency practice. However, individual agencies will have considerable flexibility to adjust the policy to meet individual conditions. As President Kennedy points out, "It is not feasible to have complete uniformity of practice throughout the Government in view of the differing missions and statutory responsibilities of the several departments and agencies engaged in research and development."

In most cases under the new policy, industry will take title to an invention resulting from a government R&D contract; the Government will receive a royalty-free license to use the invention. This will serve the public interest by making it more likely that the invention would be developed and put to commercial use than if the invention were made more freely available, the President says.

However, the Government will take title to patents where:

- The contract is in a field where the Government has done most of the work or financed most of the work.
- The contract explores fields which directly concern public health or welfare.
- The contract is to develop commercial items which government regulations may require the public to use.
- The services of the contractor are for operating a government-owned research or production facility or for coordinating or directing the work of others.

In cases where a contractor takes title to a patent, he must develop the invention or lose his exclusive rights. If, within three years after a patent issues, a contractor has not taken effective steps to bring the invention to the point of practical application or made licenses available to others on reasonable terms, the Government will have the right to force the contractor to grant a license to an applicant on a nonexclusive royalty-free basis.

To keep an eye on government patent activities, the President has asked the Federal Council for Science and Technology to consult with the Justice Department and make annual reports.