The issue is whether the general headings used by the respondent represent a true statement of information regarding the specifically named side effects.

We contend that the test of a true statement has not been met through use of general headings.

2. A charge was that the ad misbranded the sample under 502(n) because it did not prominently display the name of at least one specific dosage form and quantitative ingredient information in direct conjunction with such display as required by regulation 1.105(d)(2).

The respondent attempts to defend the charge (1) by making a general denial of the validity of the regulation and (2) by implying irrationally that regulation 1.105(d)(2) is dependent on 1.105(d)(1). The fact is that 1.105(d)(2) is an independent regulation, as a careful reading will disclose.

Consistent with not proceeding toward Federal Court determination of the validity of existing advertising regulations now under revision, we do not believe that regulation 1.105(d)(2) is needed as a basis for continuing the essential element of this charge.

Section 502(n)(2) provides the basis for requiring "the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e)."

Possibly due to ignorance, the respondent appears to take comfort in relying on section 502(n)(2) as a basis for omitting quantitative ingredient information from the ad. He even goes so far as to recite the language of 502(e) to require "the label to bear . . . in case it is fabricated from two or more ingredients, the name and quantity of each active ingredient."

The fact is that Indocin Capsules, 25 mg., are fabricated from 2 or more ingredients; this means that the quantity of indomethacin (the active ingredient) in the capsule must be declared on the label and in the advertisement.

The issue here is so clear cut that it needs no further comment.

C. COMMENTS ON CERTAIN FEATURES OF THE RESPONDENTS LETTER OF FEBRUARY 6, 1968

1. The respondent claims that the contraindication that "indomethacin is contraindicated in aspirin-sensitive asthmatics" was included in labeling for the first time in a package circular put into general use on October 31, 1966. It claims, therefore, that it was not possible to make the change in this advertisement on such short notice. In this connection, the respondent states in paragraph 7 on page 13 of its letter, in relation to a separate charge of omitting a large number of specific side effects from the ad, that such side effects were only included in the labeling at the same time as the foregoing contraindication.

The respondent also claims that the period of 90 days (suggested as a guide by Dr. McCleery on January 23, 1968) for conforming promotional labeling and advertising to package labeling had not expired when the ad appeared.

It can be shown that the respondent is in error in respect to the claims regarding the timing involved.

2. Section D of the respondent's letter deals primarily with matters such as meetings between the Agency and Merck management; current more careful handling of clearances within the firm; voluntary destruction of substantial quantities of promotional material, presumably also violative; a prior citation; the fact that a prosecution would be punitive [which is admitted], etc.

We believe that such information as that presented by the respondent to show good behavior would be properly the subject of an inquiry from a probation officer. Such information is often useful in determining the amount of fine, etc. This was the case when Wallace Laboratories was prosecuted in re Pree-MT; in that case Wallace not only had undertaken massive corrective action but also took Pree-MT off the market.

We believe that the prosecution action taken against Wallace should be taken into account in determining whether Merck should be prosecuted in relation to this sample.

R. S. MCCLEERY, M.D.

MARCH 11, 1968.

DIRECTOR, BUREAU OF REGULATORY COMPLIANCE.
DIRECTOR, BUREAU OF MEDICINE.

The Bureau of Medicine recommends that prosecution of the firm be instituted, subject to approval by General Counsel. As you may note from the attached memorandum of March 8, 1968, subject as above, from the Division of Medical