venting product related injury to children, the handicapped, and senior citizens.

(7) *Probability of exposure to hazard.* The Commission may also consider several other things which can help to determine the likelihood that a consumer would be injured by a product thought to be hazardous. These are the number of units of the product that are being used by consumers, the frequency with which such use occurs, and the likelihood that in the course of typical use the consumer would be exposed to the identified risk of injury.

(8) *Additional criteria.* Additional criteria may arise that the staff believes warrant the Commission's attention. The Commission encourages the inclusion of such criteria for its consideration in establishing priorities. The Commission recognizes that incontrovertible data related to the criteria identified in this policy statement may be difficult to locate or develop on a timely basis. Therefore, the Commission may not require extensive documentation on each and every criterion before making a decision. In addition, the Commission emphasizes that the order of listing of the criteria in this policy is not intended to indicate either the order in which they are to be considered or their relative importance. The Commission will consider all the criteria to the extent feasible in each case, and as interactively or jointly as possible.

(Sec. 4, 15 U.S.C. 2053), 86 Stat. 1210; as amended by sec. 4, Pub. L. 94-284)

Effective date: October 4, 1977.

Dated: September 28, 1977.

RICHARD E. RAPPS,
Secretary, Consumer Product Safety Commission.

[FR Doc.77-29108 Filed 10-3-77;8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 76N-0311]

PART 201—LABELING

Revocation of Requirements for Aminopyrine and Dipyrone

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule revokes the regulation describing the conditions that must be met for the continued marketing of aminopyrine and dipyrone. This is being done because there are no approved new drug applications (NDA's) for either of these drug products.

DATES: Effective November 3, 1977. Comments by November 3, 1977.

ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Nathan M. Kight, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857. (301-443-3640).

SUPPLEMENTARY INFORMATION: In a statement of policy published in the FEDERAL REGISTER of November 17, 1964 (29 FR 15364) under 21 CFR 3.44 (now 21 CFR 201.311), and amended in the FEDERAL REGISTER of October 11, 1967 (32 FR 14101), the Commissioner of Food and Drugs declared aminopyrine and dipyrone to be new drugs approvable for use only for their antipyretic effect in serious or life-threatening situations where either salicylates or similar drugs are known to be ineffective, or where the benefit-to-risk considerations for dipyrone are acceptable. Applications were approved for dipyrone, but none were received for aminopyrine, which is not known to be marketed in the United States.

Dipyrone is an analgesic antipyretic drug produced in both oral and parenteral forms. It is a sodium sufonate derivative of aminopyrine and has similar properties.

The Director of the Bureau of Drugs issued a notice of opportunity for hearing in the FEDERAL REGISTER of September 3, 1976 (41 FR 37386) proposing to withdraw approval of NDA's for drug products containing dipyrone on grounds of lack of evidence of safety. In response to the notice, two firms submitted requests for hearing and requests for extension of time to file supporting data. The Food and Drug Administration denied both requests for an extension of time. One of the firms later withdrew its request for hearing. The other elected not to submit the supporting data and analysis that are required by 21 CFR 314.200 and, therefore, its request for hearing was denied. A third firm, though not electing to request a hearing for its products, did request an extension of time to file a hearing request and submitted a published study to demonstrate the safety of dipyrone. The study was reviewed and found not to be relevant to the safety issue on the basis of which the drug products containing dipyrone were being withdrawn. The request for an extension of time was denied. A notice was published in the FEDERAL REGISTER of June 17, 1977 (42 FR 30893) withdrawing approval effective June 27, 1977, of all NDA's for drug products containing dipyrone. Inasmuch as there are no approved NDA's for drugs to which § 201.311 applies, the Commissioner concludes that this regulation should be revoked.

In consideration of the foregoing, the Commissioner finds for good cause that notice and public procedure are impracticable, unnecessary, and contrary to the public interest. Interested persons may, on or before November 3, 1977, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, four copies of written comments. Identify docket number found in brackets heading of this document. Comments received may be seen in the office of the Hearing Clerk between the hours of 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation resulting by such comments will be the subject of a further amendment.

§ 201.311 [Reserved].

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502 (f) and (l) and 701(a), 52 Stat. 1051 as amended, 1055 (21 U.S.C. 352 (f) and (l) and 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 201 is amended by revoking

§ 201.311 Aminopyrine or dipyrone drug preparations for human use; directions and warnings.

Effective date. This revocation shall be effective on November 3, 1977.

(Secs. 502 (f), (l), 701(a), 52 Stat. 1051 as amended, 1055 (21 U.S.C. 352(f), (l), 371 (a)),)

Dated: September 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-29076 Filed 10-3-77;8:45 am]