

10574 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

APPENDIX III

ENFORCEMENT ALTERNATIVES AVAILABLE TO THE FOOD AND DRUG ADMINISTRATION

CRIMINAL PENALTIES

Section 301 of the FD&C Act sets forth those actions which are prohibited under the law. Section 303 provides that any person who violates a provision of section 301 be imprisoned for not more than 1 year or fined not more than \$1,000, or both. For second and subsequent convictions, the imprisonment and fine are increased to no more than 3 years or \$10,000, or both.

Citation

Section 305 of the FD&C Act provides that, before any violation of the FD&C Act is reported for institution of a criminal proceeding, the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding. To comply with this provision a Notice of Hearing, often referred to as a citation, is mailed to the alleged violator(s) and a date for response designated.

INJUNCTION

Section 302 of the FD&C Act provides for injunction to restrain violations of section 301. An injunction enjoins the firm or individual from performing or not performing some act.

SEIZURE

Section 304 of the FD&C Act provides that seizure proceedings may be initiated against any food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce.

Recall

A recall is described as voluntary action by a firm to remove from the market those products that present a threat to the safety or well-being of the consumer. Although such