

IV. TRADE SECRETS

FDA has adopted the following definition of trade secret:

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.¹

Trade secrets include such things as a company's manufacturing processes and precise product formulations. The Task Force believes that trade secrets have limited value for public disclosure, and that the value for public disclosure of other types of data, such as clinical trial results and adverse event reports, is significantly greater.

The Task Force believes that data relating to manufacturing methods and processes, which is the direct result of innovative efforts, deserves protection because keeping trade secret information confidential maintains investment in new product development and thus is important to fostering innovation.

As a result, the Task Force believes that trade secrets should remain confidential. Where such trade secrets exist in the documents proposed for public disclosure in the draft report that follows, the Task Force supports their redaction from the documents before the documents are disclosed.

FDA's current practice is to treat a substantial amount of the information that is submitted to FDA by companies and that does not fall under FDA's definition of trade secrets as confidential commercial information that is not publicly disclosed.

The Task Force examined the categories of information currently withheld as confidential commercial information. In some cases, the Task Force found that some firms are already disclosing certain information FDA currently treats as confidential commercial information. In those cases, the Task Force concluded that there may be little public benefit to withholding the information.

In other cases, the Task Force weighed the interests of the public in disclosure and the competitive interests that may be implicated by disclosure of the information currently considered confidential commercial information. Based on this assessment, the Task Force proposed how FDA should treat that information. In some instances, the Task Force is proposing that based upon this assessment, such information should be disclosed and, in other instances, the Task Force is proposing that FDA continue to treat the information as confidential. These draft proposals for public comment are discussed further in the body of this report.

Changes to statutes or regulations may be needed to implement some of the proposals.

¹ 21 C.F.R. § 20.61(a); *see also Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983).