mation which are contained in the submission(s) and which will otherwise be available for public disclosure in accordance with the principles established in this section shall be retained as confidential and exempt from public disclosure. This request must be accompanied by a statement justifying confidentiality. Any such data and information for which confidentiality is not requested or which the Food and Drug Administration concludes (in accordance with paragraph (c) of this section) are not exempt from public disclosure will be made available to the public at the end of this 180-day period. An extension in the 180-day time period will be granted upon a showing that the volume of prior submissions precludes completion of this job within that time and will be conditioned upon prompt filing of all requests for confidentiality as they are completed. The Food and Drug Administration may defer ruling upon such a request for confidentiality of specified data or information until a request for public disclosure of that data or information is received. In cases where requests for public disclosure of documents are pending the Food and Drug Administration may ask for an expedited submission on this matter. A summary of safety and functionality data and information as required by § 135.4a(b)(13) must accompany a request for confidentiality. If the request for confidentiality is granted, the summary and all nonconfidential information will be made available for public disclosure.

PART 146—ANTIBIOTIC DRUGS; PROCEDURAL AND INTERPRETATIVE REGULATIONS

8. In part 146, by adding the following new section:

§ 146.16 Confidentiality of data and information.

(a) The existence of an IND is confidential and will not be publicly disclosed unless it has been previously acknowledged by the sponsor. The Assistant Commissioner for Public Affairs will maintain a list available for public inspection of pending Forms 5. The list will disclose the name of the drug and the name of the applicant. An applicant may submit to the Food and Drug Administration a request to exclude his Form 5 from the list for good cause. The Director of the Bureau of Drugs will make the initial determination on whether good cause has been shown. If the Director concludes that good cause has not been shown, the sponsor or applicant may appeal this decision to the Assistant Commissioner for Public Affairs, whose decision on the matter will be final.

(b) Prior to the termination or discontinuation of an IND or the approval of an NDA, all data and information submitted or incorporated by reference in an IND file are confidential and not available for public disclosure except to the extent previously made public in an authorized manner by the sponsor or master file holder. All data and information submitted or incorporated by reference in any form submitted pursuant to § 146.13 or § 146.14 shall be clearly marked confidential if the sponsor or applicant considers it to be confidential and exempt from public disclosure. Adequate grounds must be given to justify the confidentiality of each item so marked. All data and information previously made public in any authorized manner will not be retained by the Food and Drug Administration as confidential unless extraordinary circumstances are shown. Any such request shall state that the data or information so specified has not previously been made available to any person who is not an employee or paid consultant or shall explain why the data or information should remain confidential in spite of such prior disclosure. Applying the guidelines in this section and in Subpart B of Part 4, the Director of the Bureau of Drugs will make the initial decision on whether information marked confidential will be available for public disclosure. If the Director concludes that an item so marked is not exempt from public disclosure, the applicant or master file holder will be so informed and will be given an opportunity to appeal that decision to the Assistant Commissioner for Public Affairs, whose decision on the matter will be final.

(d) All safety and effectiveness data and information submitted with or incorporated by reference in any form submitted pursuant to § 146.13 or § 146.14 are available for public disclosure after approval of the drug unless extraordinary circumstances are shown.

(e) A protocol for a test or study is available for public disclosure unless an adequate showing is made that it constitutes a trade secret or confidential information because it is unique, has not previously been disclosed in an authorized manner to anyone other than a company employee or a paid consultant, has been developed at significant cost, and provides a competitive advantage.

(f) Manufacturing methods or processes, including quality control procedures, are not available for public disclosure except to the extent previously disclosed to the public by the applicant or master file holder.