b. By revising § 130.32 to read as follows:

§ 130.32 Confidentiality of data and information.

(a) The existence of an IND is confidential and will not be publicly disclosed unless it has previously been acknowledged by the sponsor. The Assistant Commissioner for Public Affairs will maintain a list available for public inspection of pending NDA's. 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 NDA 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 the 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.

(c) All data and information submitted or incorporated by reference in an NDA file (including an IND, supplemental NDA, § 130.13 report, master file, or other similar submission) shall be clearly marked confidential if the 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 request for confidentiality shall state that the data or information so marked 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) Unless otherwise publicly disclosed, no safety and effectiveness data and information submitted with or incorporated by reference in an NDA file are available for public disclosure until the Food and Drug Administration withdraws approval of the NDA or determines that the drug is not a new drug or may be marketed pursuant to an abbreviated NDA. All such data and information are available for public disclosure when the Food and Drug Administration withdraws approval of the NDA or determines that the drug is not a new drug or may be marketed pursuant to an abbreviated NDA 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 sponsor or applicant or master file holder.

(g) An assay method is not available for public disclosure except to the extent previously disclosed to the public by the sponsor or applicant or master file holder unless it must be available to permit other manufacturers to comply with limits established for the drug under an old drug monograph or an abbreviated NDA. The availability of an assay method will be included in the regulation.

(h) All safety and effectiveness data and information contained in an IND file which has been discontinued or terminated are available for public disclosure unless extraordinary circumstances are shown.

(i) Adverse reaction data and information are available for public disclosure with the names and other identifying information of individuals deleted (including the person using the product and the person reporting the information).

(j) Production and sales data and information are not available for public disclosure except to the extent previously disclosed to the public.