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 Foods will make the initial determination 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 petitioner 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.

(b) All safety and functionality data and information submitted with or incorporated by reference in a petition are available for public disclosure after the regulation is promulgated unless extraordinary circumstances are shown.

(c) 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.

(d) 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 petitioner or master file holder.

(e) An assay method is not available for public disclosure except to the extent previously disclosed to the public by the petitioner or master file holder unless it must be available to permit manufacturers to comply with limits established for the additive. The availability of an assay method will be included in the regulation.

(f) Every person who has filed a petition prior to the effective date of this section may submit in writing to the Food and Drug Administration, within 180 days after such effective date, a request that specified safety, functionality, protocol, or assay data and information which are contained in the petition 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 (a) of this section) are not exempt from public disclosure will be made available to the public at the end of this 180-day period. 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.

PART 121—FOOD ADDITIVES

5. In part 121, by revising paragraph (h) in § 121.51 to read as follows:

§ 121.51 Petitions proposing regulations for food additives.

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(h) (1) All data and information submitted with or incorporated by reference in a petition shall be clearly marked confidential if the petitioner 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 rata or information should remain confidential in spite of such prior disclosure. Applying the guidelines in subparagraphs (2) through (5) of this paragraph and Subpart B of Part 4, the