(k) Quantitative or semiquantitative formulae are not available for public disclosure except to the extent previously disclosed to the public. A list of all ingredients contained in a product or a list of all products containing a specified ingredient or a list of all products known to possess a particular characteristic or any similar list is available for public disclosure. A particular ingredient (or product containing that ingredient) may be excluded from any such list upon a showing that the ingredient is a trade secret in that it is unique, is important to the product, and is not known to competitors.

(l) Every person who has submitted an IND or NDA file 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 data and information 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 decision on this matter. A summary of all safety and effectiveness data and information as required by § 130.4(c)(2)(14) 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 135—NEW ANIMAL DRUGS

7. In Part 135:

a. In § 135.4a(b), by redesignating subparagraph (13) *Assembling and binding the application* as subparagraph (15) and adding a new subparagraph (13) as follows (a new subparagraph (14) will be proposed in the near future):

§ 135.4a New animal drug applications.

* * * * * * *

(b) * * *

(13) *Summary of safety and effectiveness data and information.* A summary shall be given of all the safety and effectiveness data and information submitted with or incorporated by reference in the application (including an INAD, supplemental NADA, § 135.14a or § 135.14b report, master file, or other similar submission). The summary will be reviewed and, where appropriate, revised by the Food and Drug Administration and will be available for public disclosure when the application is approved. A current summary will be submitted by the applicant and will be reviewed and revised for each submission made subsequent to approval of the application. The summary does not constitute the full reports of investigations required under section 512(b)(1) of the act on which the safety or efficacy of the drug may be approved.

* * * * * * *

b. By revising § 135.33 to read as follows:

§ 135.33 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 NADA petitions. 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 NADA from the list for good cause. The Director