submission (e.g., as part of an IND or NDA) to the Food and Drug Administration. Should the Food and Drug Administration need the actual names of such individuals for followup purposes, a separate request will be made.

§ 4.32 Investigatory files compiled for law enforcement purposes.

No data or information contained in investigatory files compiled for law enforcement purposes (including correspondence, memoranda, test results, and information obtained from factory inspections) will be made available for public disclosure until after a decision has been made not to institute informal or formal enforcement action or until such action is completed or until the statute of limitations runs, whichever occurs first. At such time the factual information contained in the file will be made available for public disclosure except that opinions, policy recommendations, intra-agency and interagency memoranda, statements of witnesses obtained through promises of confidentiality, names of individuals, trade secrets, and other confidential information will be deleted.

§ 4.33 Situations for which confidentiality is uncertain.

In situations where the confidentiality of data or information is uncertain and there is a request for its public disclosure, the Food and Drug Administration will consult the person who has submitted the data or information before concluding whether it is available for public disclosure.

§ 4.34 Use of data or information for formal or informal actions.

Nothing in this part or this title shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is confidential, as the basis for taking any formal or informal action within its jurisdiction.

§ 4.35 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours to search and compile will be processed taking into account the man-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the procesisng of such a request for information shall be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. In any situation in which a request for information cannot fully be complied with under these circumstances, the person making the request will be asked to be more specific or to narrow the request, and an attempt will be made to provide as much of the type of data or information sought as is feasible under the circumstances.

§ 4.36 Availability of documents.

(a) In any situation where a document is available for public disclosure, but a portion of the data or information contained in the document is not available for such disclosure (e.g., it contains a trade secret or confidential information or names or individuals or law enforcement information), the portion that is not available for disclosure will be deleted before the document is disclosed to the public.

(b) A document that is ordinarily available for public disclosure (e.g., a letter within § 4.23 or a memorandum within § 4.24(b)) will not be available for such disclosure if it falls within an exemption (e.g., it is part of a law enforcement file within § 4.32 or is confidential within § 4.25).

PART 8—COLOR ADDITIVES

4. In Part 8, by revising § 8.9 to read as follows:

§ 8.9 Confidentiality of petition.

(a) 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