tained in FDA files. The general Federal confidentiality statute, section 1905, title 18 U.S.C., Crimes and Criminal Procedure (18 U.S.C. 1905), provides that:

"Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than 1 year, or both; and shall be removed from office or employment.

Section 301(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(j), prohibits:

The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, 512, 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

Section 4(h) of the Federal Hazardous Substances Act, 15 U.S.C. 1263(h), similarly prohibits:

The use by any person to his own advantage, or revealing other than to the secretary or offices or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, of any information acquired under authority of section 11 concerning any method or process which as a trade secret is entitled to protection.

Section 359(d) of the Public Health Service Act, 42 U.S.C. 263g(d), as added by the Radiation Control for Health and Safety Act of 1968 provides that:

Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any such defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 360A as he deems will assist in carrying out the purposes of this subpart, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code unless he determines that it is necessary to carry out the purposes of this subpart.

With respect to information obtained through inspection and reports on electronic products, section 360A(e) of the Public Health Service Act, 42 U.S.C. 263i, also provides that:

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsection (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this subpart or when relevant in any proceeding under this subpart. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

FDA has no authority either to grant public access to information prohibited from disclosure or to deny public access to information not exempt from disclosure. FDA has on many occasions urged a congressional review of the statutory provisions denying public access to information contained in its files, but no such review has been undertaken. Accordingly, this notice can serve only to interpret and clarify the application of existing statutory provisions. The Commissioner therefore proposes to amend the FDA regulations to reflect the following policy: