The original documents are located in Box 7, folder "Drug Safety Legislation" of the Loen and Leppert Files at the Gerald R. Ford Presidential Library.

THE WHITE HOUSE

WASHINGTON

June 2, 1976

MEMORANDUM FOR: MAX FRIEDERSDORF

FROM: JIM CANNON

SUBJECT: Drug legislation

This is to let you know that the Administration's Drug Safety Bill (H.R. 13577) was transmitted both to Congressman Carl Albert and to Vice President Rockefeller on May 27th.

open file of we don't have one.

RED TAG

THE WHITE HOUSE

WASHINGTON

May 13, 1976

MEMORANDUM FOR: JIM CANNON

THROUGH: MAX FRIEDERSDORF
CHARLES LEPPERT, JR.

FROM: PATRICK ROWLAND PR

SUBJECT: Rep. Paul Rogers (D-Fla.)

Rep. Rogers had requested the information regarding the Administration's stand on his drug bill, H.R.12391. Attached is a copy of that bill.

The proposals in his bill should not be confused with the Administration's bill which was sent up two weeks ago and introduced by Rep. Robert McClory (H.R.13577).

Roger's bill deals with the labeling of drugs and significant health hazards of pharmaceuticals, while the Administration proposals deal with illegal drug trafficking.

94TH CONGRESS
2D SESSION

H. R. 12391

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 1976

Mr. ROGERS (for himself, Mr. PREYER, Mr. SYMINGTON, Mr. SCHEUER, Mr. WAXMAN, Mr. FLORIO, Mr. CARNEY, Mr. MAGUIRE, Mr. CARTER, and Mr. HEINZ) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that labeling of drugs disclose to drug users the generic names of the drugs and information concerning side effects, adverse reactions, and related information and to authorize licensed practitioners to order in the prescription of a drug that its labeling not include such information; to strengthen the records and reports authority under that Act; to require the reporting of information respecting significant health hazards; to authorize conditional approval of new drugs; to authorize the suspension of approved new drug applications if necessary to reduce or eliminate a significant risk of illness, injury, or lack of effective treatment; to strengthen the Food and Drug Administration; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—DRUG SAFETY AMENDMENTS

SHORT TITLE AND REFERENCE TO ACT

SEC. 101. (a) This title may be cited as the "Drug Safety Amendments of 1976".

(b) Whenever in this title (other than in section 104 (b)) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the section or other provision is a section or other provision of the Federal Food, Drug, and Cosmetic Act.

PATIENT PACKAGE INSERTS

SEC. 102. (a) Section 502 is amended as follows:

(1) Effective upon the expiration of the twelve-month period beginning on the date of the enactment of this Act, clause (1) of paragraph (b) is amended to read as follows: "(1) in the case of a drug which may be dispensed only upon the prescription of a practitioner licensed by law to administer such drug, the name and place of business of the manufacturer of the final dosage form of the drug and, if different, the name and place of business of the packer or distributor and, in the case of any other drug or a device, the name and place of business of the manufacturer, packer, or distributor; and".

(2) Such section is amended by inserting after paragraph (e) the following new paragraph:

"(f) (1) (A) Unless in the case of a drug, its labeling, pursuant to regulations of the Secretary, bears, when administered or dispensed to, or purchased by, any individual—

"(i) adequate directions for use of the drug, including adequate information (in readily understandable language) respecting—

"(I) the purposes or indications for which the drug may be used,

"(II) the proper administration of the drug,

"(III) the proper storage and handling of the drug, and

"(IV) warnings against unsafe use of, and known or possible side effects and adverse reactions from the use of, the drug;

"(ii) the date (established under regulations of the Secretary) after which the drug should not be used;

"(iii) the drug's established name (as defined in paragraph (e) (2)) and its identification in accordance with an appropriate uniform identification code established under regulations of the Secretary; and

"(iv) such other information as the Secretary considers necessary for the protection of the public health.

The Secretary shall by regulation authorize practitioners who are licensed by law to administer drugs to order in the written prescription of a drug that the labeling of the drug not include the information (or any part thereof) prescribed under the first sentence of this clause. The Secretary may

promulgate regulations to exempt a drug or category of drugs from any requirement of such sentence if the Secretary determines that such requirement, as applied to the drug or to a particular circumstance of administration of the drug, is not necessary for the protection of the public health.

"(B) A regulation promulgated under the first sentence of clause (A) (other than a regulation making a clerical or similar technical change in a regulation promulgated under such sentence) shall take effect as prescribed in the regulation, but it may not take effect before ninety days after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety.

"(C) Any requirement in effect under this paragraph with respect to a drug immediately prior to the date of the enactment of the Drug Safety Amendments of 1976 shall apply to such drug until the applicability of such requirement has been changed by action taken by the Secretary under this paragraph after such date.

"(2) Unless in the case of a drug which may be dispensed only upon the prescription of a practitioner licensed to administer such drug, its labeling bears, in addition to the matter required by subparagraph (1), such information for practitioners licensed by law to administer drugs as the Secretary may establish.".

(3) Paragraph (f) is amended—

(A) by striking out "(f) Unless" and inserting in lieu thereof "(3) Unless in the case of a device",

(B) by redesignating clauses (1) and (2) as clauses (A) and (B),

(C) by striking out "dosage or",

(D) by striking out in the proviso "clause (1) of this paragraph" and inserting in lieu thereof "clause (A) of this subparagraph", and

(E) by striking out "drug or" each place it occurs in the proviso.

(b) Section 503 (b) (2) is amended by inserting "(b), (f)," after "paragraphs (a)".

(c) The Secretary of Health, Education, and Welfare shall, within the twelve-month period beginning on the date of the enactment of this Act, publish in the Federal Register a list of priorities for the promulgation of regulations under the authority of the first sentence of section 502 (f) (1) (A) of the Federal Food, Drug, and Cosmetic Act (other than the authority provided by subclause (ii) or (iii) of such sentence). Such priorities shall be based upon consideration of the frequency of the use of a drug, the frequency of occurrence of adverse effects from the use of a drug, the seriousness of such adverse effects, and a drug's potential for misuse or abuse.

RECORDS AND REPORTS

SEC. 103. (a) Chapter V is amended by inserting after section 503 the following new section:

"RECORDS AND REPORTS

"SEC. 504. (a) (1) Any person who—

"(A) may be required to register under section 510(b), or

"(B) is responsible for the clinical or preclinical investigation, on behalf of a person who may be so required to register, of a drug or substance intended for use as a drug,

shall establish and maintain such records, and make such reports to the Secretary, of such data or information (including data or information on side effects, contraindications, and precautions respecting the use of a drug) developed, received, or otherwise obtained by such person, as the Secretary by regulation or order finds are necessary to enable him to determine whether drugs are safe and effective and otherwise comply with the requirements of this Act.

"(2) Any person subject to paragraph (1) who obtains information which reasonably supports the conclusion that a drug (with respect to which such person is required to register under section 510 or which is the subject of a clinical or preclinical investigation for which such person is responsible) may present a significant hazard to human

health (including information which reasonably supports the conclusion that the drug may cause cancer or other disease in man or other animals) shall, in accordance with regulations of the Secretary, immediately submit the information and any supporting data to the Secretary, unless such person has actual knowledge that the Secretary has already obtained such information and data.

"(b) Every person required under subsection (a) to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

"(c) If the Secretary determines that any information obtained or received by him reasonably supports the conclusion that a drug introduced for commercial distribution may present a significant hazard to human health (including information which reasonably supports the conclusion that a drug may cause cancer or other disease in man or other animals) shall mail or cause to be mailed to all practitioners licensed by law to administer drugs a summary of such information.".

(b) (1) Section 301(e) is amended by inserting "504," after "under section".

(2) Section 301 (j) is amended by inserting "504," after "409,".

(3) Clause (1) of the second sentence of section 505 (e) is amended (A) by striking out "regulation or order under subsection (j)" and inserting in lieu thereof "regulation or order under section 504 or subsection (j)", and (B) by striking out "by paragraph (2) of such subsection" and inserting in lieu thereof "by section 504 (b) or subsection (j) (2)".

(4) The last sentence of section 505 (i) is repealed.

CONDITIONAL APPROVAL OF NEW DRUGS

SEC. 104. (a) Section 505 is amended by adding after subsection (j) the following new subsection:

"(k) (1) Upon approving the application for any drug under subsection (c) of this section, or thereafter, the Secretary may prescribe such conditions and limitations upon the approval of the drug's application as he deems necessary to better assure that the drug is safe and effective in use and that adequate information is obtained concerning the effects of widespread or prolonged use of the drug.

"(2) The Secretary may immediately suspend the approval of the application for any drug under subsection (c) upon a finding that a condition or limitation prescribed under paragraph (1) and applicable to the drug has not been met.

"(3) If the application for a drug is subject to conditions or limitations prescribed under paragraph (1), the information included in the directions for use of the drug under section 502 (f) (1) (A) (i) or 502 (f) (2) shall also include (in such form and manner as the Secretary prescribes) (A) a statement that the approval of the drug is subject to conditions or limitations, (B) information describing conditions or limitations applicable to the use of the drug, and (C) warnings respecting any hazard presented or which may be presented by the drug and, if appropriate, a warning that all the effects from the use of the drug are not known.".

(b) Part I of title IV of the Public Health Service Act is amended by adding at the end the following new section:

"DRUG STUDIES

"SEC. 476. (a) The Secretary, acting through the National Institutes of Health and in consultation with the Commissioner of the Food and Drug Administration, may conduct or support (by grant or contract) studies of the short-term or long-term use of any drug and of drugs with alternative forms of therapy and studies involving the comparison of drugs.

"(b) Contracts may be entered into under subsection

(a) without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

"(c) For purposes of subsection (a), there is authorized to be appropriated $10,000,000 for each fiscal year.

"(d) The Secretary shall make an annual report to the Congress respecting the activities undertaken or supported under subsection (a).".

RELEASE OF SAFETY AND EFFECTIVENESS DATA

SEC. 105. (a) Section 505 is amended by adding after subsection (k) (added by section 104 of this Act) the following new subsection:

"(l) (1) The Secretary shall promulgate regulations under which a detailed summary of information which relates to the safety and effectiveness of any drug, which was submitted to the Secretary, and which was the basis for—

"(A) an order under subsection (c) of this section approving an application for approval for such drug or denying approval of such an application,

"(B) an order under subsection (e) of this section withdrawing approval of such an application for such drug,

"(C) an order disapproving, or terminating an investigational exemption for such drug under subsection (i) of this section, or

"(D) an order under subsection (k) of this section suspending approval of such drug's application,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a drug shall include a summary of any information respecting adverse effects on health presented by the drug, including any information indicating that the drug may cause cancer in man or other animals, and an explanation of the basis upon which the Secretary has found that the benefits from use of the drug do, or do not, exceed the risks presented by its use.

"(2) Any information respecting a drug which is made available pursuant to paragraph (1) of this subsection (A) may not be used to establish the safety or effectiveness of another drug for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to section 301 (j).".

(b) Section 512 is amended by adding after subsection (m) the following new subsection:

"(n) (1) The Secretary shall promulgate regulations under which a detailed summary of information which relates to the safety and effectiveness of any new animal drug or any animal feed bearing or containing a new animal drug,

which was submitted to the Secretary, and which was the basis for—

"(A) an order under subsection (c) or (m) (2) of this section approving an application with respect to such a drug or feed or denying approval of such an application,

"(B) an order under subsection (e) or (m) (4) of this section withdrawing approval of such an application with respect to such a drug or feed, or

"(C) an order disapproving, or terminating an investigational exemption for such drug under subsection (j) of this section,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a drug or animal feed shall include a summary of any information respecting adverse effects on health presented by the drug or animal feed, including any information indicating that the drug may cause cancer in man or other animals, and an explanation of the basis upon which the Secretary has found that the benefits from use of the drug do, or do not, exceed the risks presented by its use.

"(2) Any information respecting a drug or animal feed which is made available pursuant to paragraph (1) of this subsection (A) may not be used to establish the safety or effectiveness of another drug for purposes of this Act by any

person other than the person who submitted the information so made available, and (B) shall be made available subject to section 301 (j).".

SUSPENSION OF APPROVED APPLICATION FOR NEW DRUG

SEC. 106. (a) Clause (2) of the first sentence of section 505 (e) is amended by inserting before the semicolon at the end a comma and the following: "or that the risk of illness or injury or lack of effective treatment from the use of the drug outweigh any benefits resulting from such use taking into account other available drugs or other forms of therapy".

(b) The first sentence of such section is amended by striking out ": *Provided*, That" and all that follows in such sentence and inserting in lieu thereof a period and the following: "If the Secretary finds that the immediate suspension of the approval of an application of a drug is necessary to reduce or eliminate a significant risk of illness, injury, or lack of effective treatment from use of the drug, the Secretary may suspend the approval of the application immediately if he gives the holder of the application prompt notice of the suspension and affords him an opportunity for an expedited hearing on the suspension.".

(c) The last sentence of section 505 (h) is amended by inserting before the period a comma and the following: "and in the case of an order under subsection (e) the court may order the stay of such order only if the court finds

that the continued availability of the drug is essential for persons being treated with it".

TITLE II—FOOD AND DRUG ADMINISTRATION

SHORT TITLE

SEC. 201. This title may be cited as the "Food and Drug Administration Act".

ESTABLISHMENT OF ADMINISTRATION

SEC. 202. Chapter IX of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 902 the following new sections:

"FOOD AND DRUG ADMINISTRATION

"SEC. 903. There is established a Food and Drug Administration (hereinafter referred to as the 'Administration') within the Department of Health, Education, and Welfare.

"COMMISSIONER

"SEC. 904. (a) APPOINTMENT.—The individual who on the date of enactment of this Act holds the office of Commissioner of Food and Drugs, Department of Health, Education, and Welfare, shall be the initial Commissioner of the Administration. Each subsequent Commissioner of the Administration shall be appointed by the President, by and with the advice and consent of the Senate. The Commissioner shall administer and enforce the laws subject to his jurisdiction.

(b) CHIEF COUNSEL.—The Commissioner shall appoint a Chief Counsel for the Administration.

"(c) POWERS.—In order to fulfill his duties under this title, the Commissioner is empowered to—

"(1) direct and coordinate the activities of the Administration;

"(2) select, appoint, or employ all personnel of the Administration and direct and supervise all personnel so selected, appointed, or employed;

"(3) employ experts and consultants in accordance with section 3109 of title 5, United States Code, and compensate individuals so employed for each day (including traveltime) at rates not in excess of the maximum rate of pay for grade GS–18 as provided in section 5332 of title 5, United States Code, and, while such experts and consultants are so serving away from their homes or regular place of business, to pay such employees travel expenses and per diem in lieu of subsistence at rates authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently;

"(4) appoint advisory committees composed of such private citizens and officials of the Federal, State, and local governments as he deems desirable to advise him with respect to his functions under the laws subject to his jurisdiction, and to pay such members (other than those regularly employed by the Federal Government) while attending meetings of such committees, or other-

wise serving at the request of the Commissioner, compensation and travel expenses at the rate provided for in paragraph (3) of this subsection with respect to experts and consultants;

"(5) promulgate such regulations as may be authorized in the laws subject to his jurisdiction;

"(6) issue subpenas reasonable in scope and otherwise consistent with law to require the attendance and testimony of witnesses and the production of documentary evidence relevant to any matter within his statutory authority which is the subject of a public hearing required by statute;

"(7) make such investigations as he deems necessary to determine whether any person has violated any provision of the laws subject to his jurisdiction. If the Commissioner has reasonable grounds for believing that any person has violated or is about to violate any such law and incorporates such grounds in a written finding to the effect that such a violation has occurred or is about to occur, the Commissioner may, prior to the institution of any civil or criminal proceeding with respect thereto, and pursuant to regulations promulgated in accordance with section 553 of title 5 of the United States Code, (A) issue a demand upon such person to produce specified documentary evidence relevant to such

possible violation for examination, and (B) require by orders filed by him the submission of answers in writing to specific questions relevant to such possible violation. Any such demand or order shall include a copy of the written finding respecting such person's possible violation and shall include advice concerning such person's constitutional right not to answer. The district courts of the United States shall have jurisdiction to enforce such subpenas or orders or to require the production of such documentary evidence upon application of the Attorney General or, as provided in subsection (d), the Commissioner. An action for such enforcement may be brought in any district court of the United States for the district wherein the person involved is found or transacts business;

"(8) utilize, with their consent, the services, personnel, and facilities of other Federal agencies and of State and private agencies and instrumentalities with or without reimbursement therefor;

"(9) enter into and perform such contracts, leases, cooperative agreements, grants, or other transactions as the Commissioner may deem appropriate, and on such terms as the Commissioner may deem appropriate, with an agency, or instrumentality of the United States, or with any State, commonwealth, territory, or possession, or any political subdivision thereof, or with any public

or private person, firm, association, corporation, independent testing laboratory, or institution;

"(10) accept gifts and voluntary and uncompensated services, notwithstanding the provisions of section 665 (b) of title 31, United States Code;

"(11) designate representatives to serve or assist on such committees as the Commissioner may determine to be necessary or appropriate to maintain effective liaison with Federal agencies and with State and local agencies and independent standard-setting bodies carrying out programs and activities related to the protection of consumers with respect to products subject to his jurisdiction;

"(12) construct such research or test facilities as may be necessary to carry out the purposes of the laws subject to his jurisdiction, (A) after fully utilizing the personnel, facilities, and other technical support available in other Federal agencies, (B) when authorized by the Congress to plan, design, and construct such facilities, and (C) subject to the appropriation of funds for this purpose by the Congress;

"(13) conduct public hearings anywhere in the United States to consider matters within his jurisdiction;

"(14) conduct such continuing studies, review, and investigations of deaths, injuries, diseases, other health

impairments, health and nutrition status, other related conditions, and economic losses associated with products subject to his jurisdiction as he deems necessary or appropriate;

"(15) conduct research, studies, and investigations on the safety and effectiveness of products subject to his jurisdiction and on improving the safety of such products, and test such products and develop product test methods and testing devices;

"(16) offer training in product safety investigation and test methods, and assist public and private organizations, administratively and technically, in the development of safety standards and test methods;

"(17) undertake such other activities as are necessary to carry out his duties under the laws subject to his jurisdiction, including those enumerated in other sections of such laws; and

"(18) delegate any of his functions and duties under the laws subject to his jurisdiction, other than subpena powers or powers to issue demands or orders under paragraph (7) of this Act, to other officers or employees of the Administration.

"(d) LITIGATION.—Notwithstanding any other provision of law, the Commissioner may initiate, defend, or appeal any court action arising under this Act through his own

legal representative or through the Attorney General, except that the Attorney General shall have exclusive authority to initiate prosecution of persons under section 303 of this Act.

"DUTIES OF THE COMMISSIONER

"SEC. 905. DUTIES OF COMMISSIONER.—The Commissioner shall—

"(1) enforce the laws which he is required under this Act to administer;

"(2) publish notice of any proposed public hearing in the Federal Register, and afford a reasonable opportunity for all interested persons to present relevant testimony and data;

"(3) upon request, furnish requests for legislative proposals directly to committees of Congress; and

"(4) subject to the provisions of the laws subject to his jurisdiction, take any action within his jurisdiction to make available to the public products that will promote the public health and welfare;

"(5) attempt to eliminate any product presenting an unreasonable risk of disease, injury, or death when compared to its benefit;

"(6) establish a capability within the Administration to engage in product evaluation and benefit-risk analysis;

"(7) establish an interdisciplinary epidemiology capability and undertake investigations to facilitate regulation-making and to assist in product evaluation and benefit-risk analysis;

"(8) establish a scientific capability within the Administration to assist in product evaluation, hazard detection, test method development, and quality control requirements; and

"(9) utilize field operations to conduct product evaluation, facilitate detection of conditions associated with products subject to his jurisdiction which might lead to disease, injury, or death, to monitor compliance with required levels of safety performance, to report violations, and to assist in any enforcement action taken by him.

"OBLIGATIONS OF ADMINISTRATION CONTRACTS

"SEC. 906. (a) MAINTENANCE OF RECORDS.—Each recipient of assistance under this Act pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Commissioner shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project undertaken in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or under-

taking supplied by other sources, and such other records as will facilitate an effective audit.

"(b) ACCESS TO RECORDS.—The Commissioner and the Comptroller General of the United States or their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under section 904(c)(9) under other than competitive bidding procedures.

"COOPERATION OF FEDERAL AGENCIES

"SEC. 907. (a) COOPERATION.—Upon request by the Commissioner, each Federal agency is authorized—

"(1) to make its services, personnel, and facilities available with or without reimbursement to the greatest practicable extent within its capability to the Administration to assist it in the performance of its functions; and

"(2) to furnish to the Administration such information, data, estimates, and statistics, and to allow the Administration access to all information in its possession, as the Commissioner may reasonably determine to be necessary or appropriate for the performance of the functions of the Administration as provided by this Act.

"(b) NATIONAL BUREAU OF STANDARDS.—The Commissioner is authorized to utilize the resources and facilities

of the National Bureau of Standards in the Department of Commerce with or without reimbursement, for the purpose of enforcing compliance or for other purposes related to carrying out his authorities under this Act.

"COOPERATION WITH STATES

"SEC. 908. The Commissioner shall establish a program to promote Federal-State cooperation for the purposes of carrying out this Act. In implementing such program the Commissioner may—

"(a) accept from any State or local authorities engaged in activities relating to health, safety, or consumer protection assistance in such functions as data collection, investigation, and educational programs, as well as other assistance in the administration and enforcement of this Act which he may request and which such States or localities may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and

"(b) commission any qualified officer or employee of any State or local agency as an officer of the Commissioner for the purpose of conducting examinations, investigations, and inspections.

"LIMITATION ON CONSTRUCTION AUTHORITY

"SEC. 909. LIMITATION.—No part of the funds appropriated to carry out this Act may be used to plan, design,

or construct any research or test facilities unless specifically authorized by the Congress by other law.".

AMENDMENTS TO TITLE 5

SEC. 203. (a) (1) Section 5315 of title 5, United States Code, is amended by adding at the end thereof the following new paragraph:

"(108) Commissioner, Food and Drug Administration.".

(2) Section 5316(43) of such title is repealed.

(b) Section 5316 of such title is amended by adding at the end thereof the following new paragraph:

"(140) Chief Counsel, Food and Drug Administration.".

TRANSFERS

SEC. 204. (a) TRANSFERS.—Except for any function reserved to the Secretary of Health, Education, and Welfare by subsection (e) of this section, there are transferred to the Commissioner of the Food and Drug Administration all functions of the Secretary of Health, Education, and Welfare and of officers and offices of the Department of Health, Education, and Welfare under the following provisions of law:

(1) Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) Filled Milk Act (21 U.S.C. 61 et seq.).

(3) Federal Import Milk Act (21 U.S.C. 141 et seq.).

(4) Tea Importation Act (21 U.S.C. 41 et seq.).

(5) Federal Caustic Poison Act (44 Stat. 1406).

(6) Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(7) Subpart 3 of part F of title III of the Public Health Service Act (relating to electronic product radiation).

(8) Sections 301, 308, 311, 314, 315, and 361 of the Public Health Service Act (42 U.S.C. 241, 242f, 243, 246, 247, and 264) insofar as such sections relate to food, drugs, devices, cosmetics, electronic products, and other products subject to the jurisdiction of the Commissioner.

(9) Sections 351 and 352 of the Public Health Service Act (42 U.S.C. 262, 263) (relating to biological products).

(10) Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(b) TRANSFERRED FUNCTIONS.—All functions—

(1) which are vested by statute or reorganization plan in the Secretary of Health, Education, and Welfare,

(2) which are not transferred by subsection (a) of this section, and

(3) which, immediately before the effective date

of this section, are delegated to or administered by the Food and Drug Administration,

are transferred to the Commissioner (except for any function reserved to the Secretary of Health, Education, and Welfare by subsection (e) of this section).

(c) PERSONNEL, ETC.—All personnel, property, records, obligations, commitments, and unexpended balances of appropriations, allocations, and other funds, which are used primarily with respect to any office, bureau, or function transferred under the provisions of this section are transferred to the Commissioner of the Food and Drug Administration. The transfer of personnel pursuant to this subsection shall be without reduction in classification or compensation for one year after such transfer, and this provision shall not be construed to impair the authority of the Commissioner to assign personnel during this period to carry out the functions of the Administration most effectively.

(d) COMPETITIVE EXAMINATIONS.—The Civil Service Commission shall establish criteria, in consultation with the Commissioner, when preparing competitive examinations for positions in the Administration.

(e) AUTHORITY OF THE SECRETARY.—There is reserved to the Secretary of Health, Education, and Welfare from the authority transferred to the Commissioner by subsections (a) and (b) of this section any function the performance of which—

(1) materially affects authority of the Secretary not transferred by subsection (a) or (b), or

(2) requires the resolution of major issues of national health policy.

(f) ADDITIONAL DELEGATIONS.—The Secretary of Health, Education, and Welfare may by regulation delegate such additional functions to the Commissioner as he from time to time deems appropriate.

SAVINGS PROVISION

SEC. 205. All laws relating to any office, agency, bureau, or function transferred under this title, insofar as such laws are applicable, remain in full force and effect. And orders, rules, regulations, permits, or other privileges made, issued, or granted by any office, agency, or bureau or in connection with any function transferred by this title, and in effect at the time of the transfer, shall continue in effect to the same extent as if such transfer had not occurred until modified, superseded, or repealed. No suit, action, or other proceeding lawfully commenced by or against any office, agency, or bureau or any officer of the United States acting in his official capacity shall abate by reason of any transfer made pursuant to this title, but the court, on motion or sup-

plemental petition filed at any time within twelve months after such transfer takes effect, showing a necessity for a survival of such suit, action, or other proceeding to obtain a settlement of the questions involved, may allow the same to be maintained by or against the appropriate office, agency, bureau, or officer of the United States.

EFFECTIVE DATE

SEC. 206. This title and the amendments made by this title shall take effect on the ninetieth day after the date of enactment of this Act.

94TH CONGRESS
2D SESSION

H. R. 12391

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that labeling of drugs disclose to drug users the generic names of the drugs and information concerning side effects, adverse reactions, and related information and to authorize licensed practitioners to order in the prescription of a drug that its labeling not include such information; to strengthen the records and reports authority under that Act; to require the reporting of information respecting significant health hazards; to authorize conditional approval of new drugs; to authorize the suspension of approved new drug applications if necessary to reduce or eliminate a significant risk of illness, injury, or lack of effective treatment; to strengthen the Food and Drug Administration; and for other purposes.

By Mr. ROGERS, Mr. PREYER, Mr. SYMINGTON, Mr. SCHEUER, Mr. WAXMAN, Mr. FLORIO, Mr. CARNEY, Mr. MAGUIRE, Mr. CARTER, and Mr. HEINZ

MARCH 9, 1976

Referred to the Committee on Interstate and Foreign Commerce