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January 19, 1970

TO: All Members of the SPI Food, Drug and
Cosmetic Packaging Materials Committee

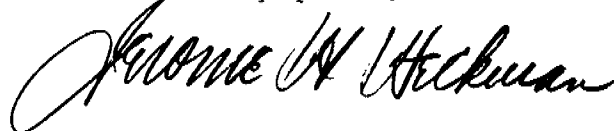
Gentlemen:

With further reference to our continuing correspondence on the reorganization of the Food and Drug Administration, I thought you would be interested in seeing the enclosed copy of a Notice that appeared in the January 16, 1970 Federal Register. As you will note, the Notice refers to the Reorganization Order issued by Secretary of Health, Education and Welfare, Robert H. Finch, and two Orders redelegating authority to the Commissioner of Food and Drugs.

Also enclosed herewith, is a copy of another very excellent article by Lou Rothschild, bearing on the FDA reorganization. This latest article by Lou appeared in the January 19, 1970 edition of Food Chemical News and I know you will find the information contained therein of great interest.

We look forward to seeing all of you at the forthcoming Committee meeting here in Washington on February 26, 1970.

Cordially yours,



Encls.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary
REORGANIZATION ORDER

Certain Functions of Department

Under the authority of section 6 of Reorganization Plan No. 1 of 1953 and section 2 of Reorganization Plan No. 3 of 1966, I hereby order reorganization of certain functions of the Department as follows:

Transfer of the Food and Drug Administration. The Food and Drug Administration, currently constituted as an organizational element of the Consumer Protection and Environmental Health Service, is hereby transferred and established within the Public Health Service as an operating agency of the Department under the direction of the Assistant Secretary for Health and Scientific Affairs.

Establishment of the Environmental Health Service. An Environmental Health Service is hereby established within the Public Health Service as an operating agency of the Department to consist of the Environmental Control Administration and the National Air Pollution Control Administration and that portion of the Consumer Protection and Environmental Health Service headquarters which was devoted to their support. The Administrator, Environmental Health Service, will continue to exercise the authorities currently delegated to the Administrator, Consumer Protection and Environmental Health Service, with the exception of the authorities delegated to the Commissioner of Food and Drugs.

Abolishment of the Consumer Protection and Environmental Health Service. The Consumer Protection and Environmental Health Service is hereby abolished.

Continuation of Regulations. Except as inconsistent with this order, all regulations, rules, orders, statements of policy, or interpretations with respect to the Consumer Protection and Environmental Health Service and to the Food and Drug Administration, heretofore issued, and either in effect immediately prior to the date of this order or to become effective subsequent to said date, are continued in full force and effect.

Prior Statements of Organization, Functions, and Delegations of Authority. To the extent inconsistent with this order, all previous Statements of Organization, Functions, and Delegations of Authority, and chapters of the Department's Organization Manual are superseded by this order, except that, pending further delegations, directives, or orders

by the Assistant Secretary for Health and Scientific Affairs, all delegations to the Surgeon General of the Public Health Service, the Administrator, Consumer Protection and Environmental Health Service, the Commissioner of Food and Drugs, and all delegations by these officials to any officer or employee of the Department, institute, bureau, division, center, or other organizational unit in effect immediately prior to the effective date of this order shall continue in effect in favor of their successors.

Relegation of appropriate administrative and managerial authorities shall be made by the Assistant Secretary for Administration and the Assistant Secretary, Comptroller, respectively, to the Commissioner of Food and Drugs.

Funds, Personnel, and Equipment. Transfers of organization and functions effected by this order shall be accompanied in each instance by direct and supporting funds, positions, personnel, records, equipment, supplies, and other resources.

Effective date: This order shall be effective February 1, 1970.

Dated: January 5, 1970.

ROBERT H. FINCH,
Secretary.

[F.R. Doc. 70-596; Filed, Jan. 15, 1970;
8:46 a.m.]

COMMISSIONER OF FOOD AND DRUGS

Redelegation by the Assistant Secretary for Health and Scientific Affairs

I hereby delegate to the Commissioner of Food and Drugs all authority delegated by the Secretary of Health, Education, and Welfare to me as follows:

1. Functions vested in the Secretary and the Department under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), the Filled Milk Act (21 U.S.C. 61-63), the Federal Import Milk Act (21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (445 Stat. 1406), the Federal Hazardous Substances Act (as amended by the Child Protection Act of 1966 and the Child Protection and Toy Safety Act of 1969) (15 U.S.C. 1261 et seq.), the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and the Flammable Liquids Act (15 U.S.C. 1201), pursuant to section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

2. Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

3. Functions pertaining to sections 301, 311, 314, and 361 of the Public Health Service Act (42 U.S.C. 241, 243, 246, and 264) which relate to pesticides, product safety, milk and food service

sanitation, shellfish sanitation, and pest control.

4. Functions under Executive Order 11001, section 3(f), and those portions of sections 3(b), 3(d), 3(e), 6, 7, 9, and 12 which relate to food, drugs, and biologicals. In the performance of these emergency functions the Commissioner shall coordinate his activities with the Administrator, Health Services and Mental Health Administration, in order that preemergency plans shall be developed in consonance with postattack organizational plans and structure of the Department for the Emergency Health Service.

5. Function of issuing all regulations of the Food and Drug Administration. The reservation of authority contained in Chapter 2-000 of the Department Organization Manual shall not apply.

6. Function of authorizing and approving miscellaneous and emergency expenses of enforcement activities, vested in the Secretary.

These authorities may be redelegated.

Pending issuance of redelegations, all delegations or redelegations to any other officer or employee of any office, institute, bureau, division, center, or other organizational unit which were in effect immediately prior to the effective date of this redelegation shall continue in effect in them or their successors.

This redelegation becomes effective February 1, 1970.

Dated: December 19, 1969.

ROGER O. ECEBERG,
Assistant Secretary for
Health and Scientific Affairs.

[F.R. Doc. 70-597; Filed, Jan. 15, 1970;
8:46 a.m.]

COMMISSIONER OF FOOD AND DRUGS

Redelegation by the Assistant
Secretary for Administration

I hereby delegate to the Commissioner of Food and Drugs all the administrative management authorities currently delegated on a common basis to heads of operating agencies within the Department of Health, Education, and Welfare.

These authorities may be redelegated within the restrictions specified in pertinent Department manual instructions or other issuances.

Pending issuance of redelegations, all delegations or redelegations to any other officer or employee of any office, institute, bureau, division, center, or other organizational unit which were in effect immediately prior to the effective date of this redelegation shall continue in effect in them or their successors.

This redelegation becomes effective February 1, 1970.

Dated: December 22, 1969.

SOL ELSON,
Acting Deputy Assistant
Secretary for Administration.

[F.R. Doc. 70-598; Filed, Jan. 15, 1970;
8:46 a.m.]

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Temporary Tolerances Set for Insecticide, Herbicide

On Jan. 15, FDA established two temporary tolerances. The agency granted to the Stored-Product Insects Research Branch of the Agricultural Research Service a tolerance of 8 p.p.m. for residues of the insecticide malathion in or on stored shelled pecans. The malathion is to be distributed under the American Cyanamid name. This temporary tolerance expires Jan. 5, 1971.

The agency granted to Ciba Agrochemical a temporary tolerance of 0.2 p.p.m. for negligible residues of 3-(4-bromo-3-chlorophenyl)-1-methoxy-1-methylurea in or on wheat (grain and straw). The temporary tolerance for the herbicide expires Jan. 7, 1971.

Four Pesticide Petitions Noted

An American Cyanamid petition noted Jan. 13 would set a tolerance of 0.1 p.p.m. in or on cottonseed for negligible residues of the insecticide 0,0,0',0'-tetramethyl 0,0'-thiodi-p-phenylene phosphorothioate and its sulfoxide (0,0,0',0'-tetramethyl 0,0'-sulfinyldi-p-phenylene phosphorothioate).

A petition filed by Uniroyal Chemical, and noted Jan. 17, would set tolerances for residues of 2-(p-tert-butylphenoxy)cyclohexyl 2-propynyl sulfite of 15 p.p.m. in or on hops, 7 p.p.m. in or on apricots and strawberries, and 4 p.p.m. in or on nectarines. A Food Additive Petition was noted the same day to set a tolerance for residues of the insecticide in or on dried hops (See story, Page 30).

Another Uniroyal petition, this one noted Jan. 13, would set tolerances for negligible residues of the herbicide sodium salt of N-1-naphthyl phthalamic acid, as follows: 0.2 p.p.m. in or on peanuts; and 0.1 p.p.m. in or on cantaloupes, castor beans, cranberries, cucumbers, muskmelons, peaches, peanut forage, plums, potatoes, pumpkins, soybeans, soybean forage, squash, sweet potatoes, and watermelons.

FMC's Niagara Chemical filed a petition, noted Jan. 17, to set a negligible residue tolerance of 0.05 p.p.m. for residues of the fungicide 1-chloro-2-nitropropane in or on cottonseed.

EDWARDS SENDS NEW FDA REORGANIZATION TO SECRETARY FINCH

Food and Drugs Commissioner Edwards last week met his self-imposed Jan. 15 deadline for reorganizing the Food and Drug Administration, and shipped his plans for a new three-bureau agency to Health, Education and Welfare Secretary Finch (See FOOD CHEMICAL NEWS, Jan. 12, Page 35).

Finch is expected to give the reorganization, which had already been previewed to Assistant Secretary for Health Roger Egeberg and Deputy Under Secretary Frederic Malek, quick approval, and allow Edwards to begin filling in the names. Official release to the staff is planned for Friday.

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Several appointments have already been made quietly, but the Commissioner has kept these under wraps.

New Assistant Commissioner for Program Coordination Established

The new organization also carries changes in the structure of the Commissioner's Office. Foremost is the appointment of a new Assistant Commissioner for Program Coordination, who is expected to "honcho" Edwards' special projects, and make sure that most elements of FDA are in communication with each other. One of Edwards' pet peeves has been the lack of communication within FDA.

The new Assistant Commissioner will have, in addition to a special projects function, jurisdiction over FDA's scientific information and computer services, and policy management, the former inspector general or "spy" functions that were transferred to the Consumer Protection and Environmental Health Service.

The Office of Policy Management will be part of the 150 or so former FDA-ers, representing about \$2.5 million in operational funds, who are coming back to FDA as a result of Finch's decision to break FDA away from CPEHS. This loss of personnel, and CPEHS' interference with FDA operations prompted the so-called Malek study which resulted in the shakeup at FDA, and the resultant split of the agency away from CPEHS (See FOOD CHEMICAL NEWS, Dec. 15, Pages 3 and 8).

In other changes, the Assistant Commissioner for Field Coordination will pick up the States Relation Services, which are now part of the Office of Legislative and Governmental Services, to add to his laboratory, inspection, and program analysis services.

The former OLGS will now handle principally FDA's contacts on Capitol Hill, and will be renamed the Office of Legislative Services.

The office of the Assistant Commissioner for Education and Information will pick up the Consumer Education Service operations of the Bureau of Compliance along with the newly established Training Institute in addition to the press services and publications it now operates.

The functions of the Assistant Commissioner for Planning and Evaluation will be unchanged, with staffs charged with planning, evaluations, and operations research.

Executive Officer Will Be Upgraded to Assistant Commissioner Again

The Executive Officer will be restored to his former position of Assistant Commissioner for Administration, with Divisions of Financial Management, General Services, Management Systems, and Personnel Management.

More power and personnel will be placed in the offices of the Associate Commissioners for Science and for Compliance, but organizationally these will remain much the same in the first phase of FDA's reorganization.

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Edwards apparently plans additional changes as time goes on and he gains experience and becomes more familiar with agency operations.

At the Bureau levels, the Bureau of Veterinary Medicine remains virtually the same, with a few personnel additions from the former Bureau of Compliance, who have been handling work for BVM, and the prospect that some of the Bureau of Science personnel who have been working with BVM also will be transferred directly into the Bureau.

The new Bureau of Foods, Pesticides, and Product Safety and the Bureau of Drugs will each have a Director, Assistant Directors for Planning and Scientific Coordination, and Executive Officers.

The Bureau of Foods will have Offices of (1) Nutrition and Food Sciences, (2) Compliance, and (3) Pesticides and Product Safety.

Under the Office of Compliance will be the Divisions of (1) Case Guidance, (2) Industry Services, (3) Sanitation Control, (4) Regulations and Petitions Control; and (5) Compliance Programs.

The Office of Nutrition and Food Sciences is virtually taken intact from the Bureau of Science and is composed of Divisions of (1) Food Chemistry and Technology, (2) Toxicology, (3) Nutrition, (4) Microbiology, (5) Colors and Cosmetics, and a new (6) Pathology Division.

New Products Research Division to be Established

The Office of Pesticides and Product Safety will be made up of Divisions of (1) Pesticide Chemistry and Toxicology; (2) Pesticide Community Studies; (3) Hazardous Substances; (4) Safety Services; (5) Poison Control; and (6) a new Product Research Division for which funds will be earmarked in FDA's 1971 fiscal year budget.

In the Bureau of Drugs, FDA will establish Offices of (1) New Drugs, (2) Marketed Drugs, (3) Pharmaceutical Sciences, and (4) Compliance.

Pharmaceutical Sciences will be composed of a Division of Drug Chemistry and a Division of Drug Biology plus the National Center for Drug Analysis in St. Louis and the National Center for Antibiotic and Insulin Analysis in Washington.

The Office of Compliance will have Divisions of (1) Rx Drug Advertising, (2) Industry Services, (3) Case Guidance, (4) Regulations, (5) Compliance Programs, and (6) Medical Review.

The Offices of New Drugs and Marketed Drugs will be largely unchanged and will be set up along present lines of disease categories, and will include some elements of the former Offices of Medical Review and Medical Support.

Edwards plans a number of changes at all levels of the organization, and is considering bringing a number of FDA-ers from the field to fill key posts. He also has been interviewing outsiders for positions, and hopes to make as many appointments as quickly as possible.

As a result of the reorganization, part of the move from Virginia and elsewhere to new offices in the Parklawn Building in Rockville, Md., will be delayed for several weeks. Edwards wants to put most of the reorganization into effect, and avoid additional relocations that might be necessary if the move goes on as scheduled. Most of the new Bureau of Foods operations will be in FB 8 in Washington, and Edwards wants to locate as many as possible of the Bureau's personnel in Washington as soon as CPEHS lets go of the space it now holds there.

In an appearance at the National Press Club last week, Secretary Finch also talked of reorganization plans, noting that he expects to propose further reorganization of HEW early this year. He indicated that the job of Assistant Secretary of Health will be upped to an Under Secretary level (See FOOD CHEMICAL NEWS, Dec. 22, Page 3).

Finch Talks of Splitting HEW into Separate Departments, but Not Now

He said he favors splitting HEW into separate Departments of Health and of Education some time in the future, but added that "now is not the time." Asked about rumors that HEW will replace its top public information officers, who are civil service employees, with political appointees, Finch replied that he has "no intention at this point" of changing "current policy."

Finch was asked about comments by former FDA Commissioner Ley to the effect that he was placed under tremendous pressure from the drug industry. Finch commented that FDA gets "pressure from all sides," indicating that this is right. He said he will not "try to isolate" FDA from pressures. Expressing "great respect for Ley," Finch said that "no one ever asked him to compromise his position."

Rogers Wants to Shift FDA's Scientific Responsibilities to NIH

In other talk of reorganization, Rep. Rogers (D-Fla.), who headed a special House Commerce Committee study of the so-called Kinslow Report on FDA, told the annual convention of the Toilet Goods Association in Miami Beach that he favored a transfer of FDA's scientific responsibilities to the National Institutes of Health where they could be separated from "police work." He said he has legislation in mind that would make the transfer. Rogers also said the objective could be accomplished by the use of a "peer review committee composed of outside scientific experts."

"The scientific responsibilities of FDA should be separated from the inspection and enforcement functions by placing the scientific responsibilities under the umbrella of NIH so as to divorce scientific determinations from regulatory and political considerations," he said, adding that this move "would also have the

added benefits of attracting the caliber of scientists needed because of the high regard in which NIH is held by the scientific and academic community."

Rogers indicated he would call Edwards and Assistant Secretary Egeberg before the Interstate Health subcommittee "to explain in more detail the reasons behind the reorganization."

NACA OPPOSES HEW VETO OVER PESTICIDE REGISTRATIONS

The National Agricultural Chemicals Association, in a letter to Health, Education and Welfare Secretary Finch, has urged against amendment of the Federal Insecticide, Fungicide and Rodenticide Act to give HEW and the Interior Department veto powers over pesticide registrations.

The point was made in comments submitted to Finch on the recommendations of the Mrak Commission on persistent pesticides (See FOOD CHEMICAL NEWS, Nov. 17, Pages 3, 6, 11, and 14; Nov. 24, Page 31; Dec. 29, Page 5; and Jan. 12, Page 19).

The Mrak Commission recommended that HEW and USDI be given the right of approval before the Agriculture Department registers pesticides. Finch initially indicated that this could be worked out by a re-write of the Inter-departmental Agreement, but more recently has called for amendment of FIFRA. The HEW change in position was based on USDA's contention that it bears sole legislative responsibility for pesticide registrations. NACA took the USDA position in the dispute.

The Association said the recommendation of the Mrak Commission "compels two inferences:

"(1) The registrant would be expected to submit directly to HEW the data to demonstrate that the proposed pesticide use would not produce untoward effects on two or more species of animals which might indicate a hazard to health. Presumably, the registrant would be expected to deal directly with HEW personnel in discussing the data. Presumably, the registrant would likewise be expected to submit data relating to effects on wildlife directly to the Department of the Interior.

"(2) The Secretary of HEW would make the decision on whether the proposed pesticide use presents an untoward hazard to the public health and the Secretary of USDI would make the decision on whether the proposed usage presents an untoward hazard to wildlife and the environment."

Mr. Miller next noted that in January, 1969, Ralph L. Harding, Jr., Executive Vice President of SPI, received a communication from the Tea Association of the United States of America, Inc., expressing interest in knowing if SPI has facilities for investigating the possibilities for transporting tea in plastic containers from growing areas overseas to blending plants in North America. Here again, Mr. Miller said he asked Mr. Heckman to send this particular communication from the Tea Association to all members of the Committee so that individual representatives could communicate directly with the Tea Association if they so desired. In this particular case, Mr. Miller indicated that he did not know whether individuals have written directly to the Tea Association or not since he has not received any additional information in this connection.

Concluding his remarks dealing with general interest items, Mr. Miller reminded everyone that, at the last meeting of the Committee, questions were raised concerning reports about a Swedish company's development of an allegedly degradable plastic beer bottle. He then read an item from the Journal of Commerce dated January 8, 1968 to the effect that this particular beer container has been taken off the market because, as the article pointed out, "insufficiently founded claims regarding the degradability" were found. The Journal of Commerce article read, in toto, as follows:

"BEER CONTAINER TAKEN OFF MARKET

"The so-called 'degradable' beer container announced last spring in Sweden by Warby Breweries has been withdrawn from the market because of 'insufficiently founded claims regarding degradability.'

"Even as originally claimed the container was not degradable in the sense that the announcement implied or as reported in the American press. It was said to take two years to 'dissolve' and therefore could not be regarded as a valid answer to any part of the litter problem.

"No suiting beverage container material known to the packaging industry today, either in the U. S. or in Europe, has the quality of degradability envisioned by those concerned with the role of packaging in litter."

Mr. Miller next called on Mr. Condit to discuss a recent move made by Ralph L. Harding, Jr., to set up within the Society a so-called "Medical Review Board" to assist in handling inquiries which the Society receives from time to time from the medical profession. Mr. Condit noted that, for the first time, a very successful meeting on plastics and the human body was held by SPI at its major National Conference in November 1968 in Chicago during the National Plastics Exposition. The speakers at this particular meeting were eminently qualified to discuss such subjects as disposable plastics in dentistry, plastics for the repair of war casualties, plastics in the artificial kidney, plastics blood vessels, plastics for assisting the failing heart, plastic heart and heart valves, and other cardiovascular uses of plastics. (Please Note: Although not all of the speakers at the National Conference provided the Society with complete copies of their talks, it has occurred to the Secretary that, if anyone is desirous of receiving copies of those papers that are available, he would be pleased to comply with requests for the same while the supply lasts.)

At a special luncheon held in November for those from the medical profession who spoke at the National Conference, Mr. Harding was advised that it would be of immeasurable assistance if SPI could act as something of a clearinghouse for inquiries about plastics and their potential applications from physicians, hospitals, and other medical personnel or institutions.

Thereafter, in May of this year, Mr. Harding communicated with the principal raw materials producers within the plastics industry querying them on the names of individuals within their companies who might be willing and able to answer the sort of questions expected to be posed by physicians. In his communication he noted that, once a list was compiled, SPI would "then operate a reference service concerning the inquiries sent to us, and in maintaining a listing of available sources of information, plan to send against this listing, from time to time the various medical inquiries which the Society receives."

Mr. Condit continued by saying that once the Society has compiled the names of those within the materials producers companies who are receptive to receiving these medical questions, SPI will announce through an appropriate press release to various medical groups, the news media, and the medical publications, that SPI is prepared to consider answering appropriate inquiries about plastics for medical applications as they are received.

Mr. Condit concluded his remarks by saying that, thus far, fine cooperation has been received from the materials companies in that several names of individuals have been provided to the Society, i.e., names of those who would be receptive to receiving the medical inquiries as they are received at the SPI headquarters.

Report of SPI Counsel

Chairman Miller then called upon Jerome H. Heckman, Esquire, Legal Counsel for SPI, to conduct his regular discussion on FDA regulatory matters.

Mr. Heckman first reported on miscellaneous matters of general interest concerning (1) changes in personnel at FDA; (2) the possibility that most of the FDA Staff (but not the Petitions Control Branch) of the FDA will be moving their offices to Rockville, Maryland; (3) the use which FDA officials are making of the so-called "Good Manufacturing Practices Manual" developed by this Committee some years ago and issued through SPI; and (4) a detailed questionnaire sent by the so-called "Kennedy Subcommittee" to all administrative agencies of the government in order to generate answers to several broad questions about procedural policies. The major situation with which he dealt at length during his discussion was the so-called "Ramsey proposal" for amending Section 121.2500 of the Food Additive Regulations, and its implications as an aftermath to the National Conference on Indirect Food Additives.

Due to the nature of Mr. Heckman's report, it was presented in a rather informal manner to permit considerable cross-questioning and explanations occasioned by the expressed interests of the members of the Committee. For this reason, instead of the usual type of formal report, there is attached to this set of Minutes, as Exhibit B, an edited transcript of Mr. Heckman's presentation, as interrupted from time to time, by questions and responses thereto, as well as comments from the floor. This material was taped during the course of the meeting so, in some