FDA GUIDELINES FOR CHEMISTRY AND TECHNOLOGY REQUIREMENTS OF FOOD ADDITIVE PETITIONS

I. PROTOCOL FOR DIRECT ADDITIVES

A. IDENTITY AND COMPOSITION - - INFORMATION SATISFYING 121.51 IN THIS AREA MAY BE FURNISHED IN THE FORM OF A COMPREHENSIVE MONOGRAPH.

1. NAME OF THE FOOD ADDITIVE: A. COMMON NAME: ESTABLISHED OR PROPOSED, IF ANY; B. CHEMICAL NAME FOLLOWING THE NOMENCLATURE OF CHEMICAL ABSTRACTS; C. OTHER NAMES IN USE, INCLUDING TRADE NAMES.

2. FORMULA: A. EMPIRICAL FORMULA; B. STRUCTURAL FORMULA, IF KNOWN OR PROPOSED; C. MOLECULAR WEIGHT.

3. DEFINITION AND DESCRIPTION OF THE FOOD ADDITIVE, INCLUDING ITS COMPLETE QUANTITATIVE COMPOSITION: LIQUID, SOLID, CRYSTALLINE, AMORPHOUS, COLOR, ODOR, TASTE, ETC. BRIEF DESCRIPTION OF THE MANUFACTURING PROCESS, INCLUDING A LIST OF ALL SUBSTANCES USED TOGETHER WITH THEIR SPECIFICATIONS AND THE EQUATIONS FOR ALL CHEMICAL REACTIONS INVOLVED. ANY PRODUCTION CONTROLS EMPLOYED TO ASSURE A REPRODUCIBLE PRODUCT SHOULD BE DESCRIBED.

4. PHYSICAL, CHEMICAL, AND/OR BIOLOGICAL PROPERTIES, SPECIFICALLY INCLUDING INFORMATION OR DATA ON STABILITY AND ALSO ALL OTHER PROPERTIES WHICH MAY BE APPROPRIATE, SUCH AS M.P., B.P., SOLUBILITY, SPECIFIC GRAVITY, REFRACTIVE INDEX, VISCOSITY, OPTICAL ROTATION, PH, ACIDITY, OR ALKANILITY, ASH, WATER CONTENT, IODINE NUMBER, SAPONIFICATION NUMBER, ALKOXYL CONTENT, VOLATILE MATTER, WATER-SOLUBLE MATTER, ETHER-EXTRACTABLES, BIOLOGICAL ACTIVITY, ABSORPTION SPECTRA IN THE ULTRAVIOLET AND INFRARED, FLUORESCENCE SPECTRA, READILY CARBONIZABLE SUBSTANCES, READILY OXIDIZABLE SUBSTANCES, ETC. WILL ALSO APPEAR IN 5(A) OR 5(C) WHEN REQUIRED.

5. SPECIFICATION FOR FOOD GRADE: A. IDENTITY - - INCLUDE SPECIFICATIONS USEFUL IN IDENTIFYING THE FOOD ADDITIVE AND METHODS FOR CHECKING THE SPECIFICATIONS; B. ASSAY - - SPECIFICATION PRESCRIBING THE MINIMUM CONTENT OF THE DESIRED COMPONENT(S). ASSAY PROCEDURE DESCRIBED IN FULL WITH VALIDATION DATA. DATA SHOWING THE RANGE OF ASSAYS AND THAT THE ASSAY SPECIFICATION CAN BE MET; C. IMPURITIES - - SPECIFICATIONS LIMITING TOTAL HEAVY METALS (U.S.P. OR ACS TEST) AND SPECIFICALLY LIMITING ARSENIC AND LEAD AND ALSO OTHER UNDESIRABLE IMPURITIES SUCH AS REACTION BY-PRODUCTS TO THE LOWEST LEVELS CONSISTENT WITH GOOD MANUFACTURING PRACTICE. DETAILS OF TESTS FOR CHECKING THE SPECIFICATIONS. DATA FROM A SUITABLE NUMBER OF REPRESENTATIVE BATCHES SHOWING THE RANGE OF IMPURITIES AND THAT THE SPECIFICATIONS CAN BE MET;

6. ANY OTHER PERTINENT INFORMATION.

B. USAGE AND LABEL SPECIMEN - - INFORMATION SHOULD BE FURNISHED SHOWING THE QUANTITY OF THE FOOD ADDITIVE PROPOSED FOR USE AND THE PURPOSE FOR WHICH IT IS PROPOSED, TOGETHER WITH ALL DIRECTIONS, RECOMMENDATIONS, AND SUGGESTIONS REGARDING THE PROPOSED USE, AND A SPECIMEN OF THE PROPOSED LABELING. THE MAXIMUM AS WELL AS THE AVERAGE QUANTITY OF THE FOOD ADDITIVE TO BE EXPECTED IN INDIVIDUAL FOODS OR TYPES OF FOODS AND IN THE TOTAL DAILY DIET OF THE CONSUMER IS TO BE ESTIMATED FOR THE USAGE PROPOSED; AND THE BASIS FOR THE ESTIMATION IS TO BE DESCRIBED IN DETAIL INCLUDING ANY ASSUMPTIONS MADE AND THE ARITHMETICAL COMPUTATIONS. USING ADEQUATE METHODOLOGY, DATA SHOULD BE SUBMITTED SHOWING THE FATE OF THE FOOD ADDITIVE IN FINISHED FOOD READY-TO-EAT, WHETHER THE FOOD ADDITIVE REMAINS UNCHANGED IN SUCH FOOD OR WHETHER IT IS CONVERTED TO ANOTHER SUBSTANCE BY REASON OF OXIDATION, DEGRADATION, OR REACTION WITH COMPONENTS OF THE FOOD, AND THE DEGREE OF ANY SUCH CONVERSION.

C. DATA ON INTENDED EFFECT IN FOOD - - EXPERIMENTAL DATA SHOULD BE SUBMITTED SHOWING THAT THE FOOD ADDITIVE WILL PRODUCE THE INTENDED EFFECT IN FOOD AND THAT THE USAGE LEVEL SOUGHT DOES NOT EXCEED THE QUANTITY OF THE ADDITIVE REASONABLY REQUIRED TO PRODUCE SUCH EFFECT. DATA FROM CAREFULLY CONTROLLED EXPERIMENTS SHOWING THE DEGREE OF EFFECT ACCOMPLISHED BY THE ADDITIVE AT GRADUATED LEVELS OF ADDITION TO FOOD MUST BE OBTAINED. THE NUMBER OF GRADUATED LEVELS WILL DEPEND UPON A NUMBER OF FACTORS, SUCH AS THE TOXICITY OF THE ADDITIVE, THE PARTICULAR FOODS INVOLVED, THE PROPOSED USAGE LEVEL, AND THE INCREMENT OF THE ADDITIVE REQUIRED TO INDUCE ANY NOTICEABLE CHANGE IN THE EFFECT ON THE FOODS. IF THE LEVEL OF USAGE IS CONSIDERED BY THE PETITIONER TO BE SELF-LIMITING, THE REASONS SHOULD BE EXPLAINED AND DATA FURNISHED SHOWING WHAT EXCESSIVE LEVEL OF THE ADDITIVE WILL PRODUCE AN UNACCEPTABLE PRODUCT.

SAMPLES. TO BE FURNISHED ONLY ON REQUEST. IN ORDER TO ASSIST US IN EVALUATING THE INTENDED EFFECT IN FOOD, WE SHALL USUALLY REQUIRE SAMPLES OF THE FOOD ADDITIVE AND SAMPLES OF FOOD REFLECTING USAGE OF THE ADDITIVE, TOGETHER WITH APPROPRIATE CONTROL SAMPLES. THE SAME SAMPLES MAY OCCASIONALLY SERVE BOTH THE PURPOSE OF METHODOLOGY TESTING DISCUSSED BELOW AND OF DEMONSTRATING THE INTENDED TECHNICAL EFFECT IN FOOD.

D. METHODOLOGY - - IF USAGE OF THE FOOD ADDITIVE REQUIRES A TOLERANCE FOR THE FOOD ADDITIVE OR FOR ITS CONVERSION PRODUCT(S) TO PROTECT THE PUBLIC HEALTH, A PRACTICABLE METHOD WILL HAVE TO BE FURNISHED TO ENFORCE THE TOLERANCE. IT MUST BE SATISFACTORY FOR APPLICATION TO THE RAW, PROCESSED, AND/OR FINISHED FOOD, I.E., GIVE CONSISTENT RESULTS, WHEN USED BY ANY PROPERLY EQUIPPED AND TRAINED LABORATORY PERSONNEL. THE METHOD MUST BE CAPABLE OF QUANTITATIVELY DETERMINING THE FOOD ADDITIVE OR ITS CONVERSION PRODUCT(S) IN THE PRESENCE OF THE NORMAL COMPONENTS OF THE FOOD IN WHICH IT IS TO BE USED AND IN THE PRESENCE OF ANY OTHER CHEMICALS, INCLUDING FOOD ADDITIVES, THAT CAN REASONABLY BE EXPECTED TO BE PRESENT IN SUCH FOOD. VALIDATION DATA MUST BE INCLUDED, I.E., BLANKS (UNTREATED FOOD) AND RECOVERIES (FOOD AND ADDITIVE AT VARIOUS LEVELS, INCLUDING LEVEL OF USAGE), SUFFICIENT TO DEMONSTRATE THE ACCURACY AND REPRODUCIBILITY OF THE METHOD.

II. PROTOCOL FOR INDIRECT ADDITIVES
(MIGRANTS FROM FOOD-PACKAGING AND FOOD-PROCESSING EQUIPMENT)

A. IDENTITY AND COMPOSITION:

1. NAME OF EACH SUBSTANCE IN THE FOOD-CONTACT SURFACE, OR LIKELY TO MIGRATE TO THE FOOD CONTACT SURFACE, INCLUDING POLYMERIC MATERIALS: A. COMMON NAME, IF ANY; B. CHEMICAL NAME FOLLOWING THE NOMENCLATURE OF CHEMICAL ABSTRACTS; C. OTHER NAMES IN USE, INCLUDING TRADE NAMES.

2. FORMULA OF EACH IN A.1: A. EMPIRICAL FORMULA; B. STRUCTURAL FORMULA, IF KNOWN OR PROPOSED; C. MOLECULAR WEIGHT: FOR POLYMERS, THE MOLECULAR WEIGHT DISTRIBUTION IN THE BASIC RESIN AND THE AVERAGE MOLECULAR WEIGHT, CITING METHODS USED.

3. QUANTITATIVE COMPOSITION OF THE FOOD-CONTACT SURFACE OF THE PACKAGING MATERIAL (PAPER, CELLOPHANE, PLASTIC FILM OR SHEET, RUBBER, AND/OR POLYMERIC COATING) OR OF THE FOOD-PROCESSING EQUIPMENT: A. BASIC RESINS POLYMERS; B. ADJUVANTS: PLASTICIZERS, STABILIZERS, PRESERVATIVES, FILLERS, COLORANTS, ETC.; C. IMPURITIES: HEAVY METALS, MONOMER, CATALYST RESIDUES, ETC.

4. DESCRIPTION OF THE MANUFACTURING PROCESS, INCLUDING A LIST OF ALL SUBSTANCES USED TOGETHER WITH THEIR SPECIFICATIONS AND THE EQUATIONS FOR ALL CHEMICAL REACTIONS INVOLVED. ANY PRODUCTION CONTROLS EMPLOYED TO ASSURE A REPRODUCIBLE PRODUCT SHOULD BE DESCRIBED.

5. PHYSICAL, CHEMICAL, AND/OR BIOLOGICAL PROPERTIES. SAME AS FOR DIRECT ADDITIVES. APPLICABLE TO EACH SUBSTANCE WHICH MIGRATES TO FOOD UNDER THE CONDITIONS OF USE. PROVIDE THE VAPOR PRESSURE OF EACH SUBSTANCE PROPOSED FOR USE IN THE PACKAGING OF DRY FOODS AND FOR ALL USES IN FOOD-PACKAGING ADHESIVES. WILL ALSO APPEAR IN A.6 WHEN REQUIRED.

6. SPECIFICATIONS OF IDENTITY AND PURITY. INCLUDE SPECIFICATIONS FOR EACH SUBSTANCE OF THE FOOD-CONTACT SURFACE IN THE PACKAGING MATERIAL USEFUL IN IDENTIFYING IT AND ASSURING IT TO BE OF SUITABLE GRADE FOR THE PURPOSE. ALWAYS INCLUDE THE MANUFACTURER'S SPECIFICATIONS FOR PURPOSES OF INFORMATION, WHETHER OR NOT PETITIONER DEEMS THEM NECESSARY IN THE REGULATION. PROCEDURES FOR CHECKING ANY NEEDED SPECIFICATIONS SHOULD BE FURNISHED; AND DATA REFLECTING SAMPLES FROM REPRESENTATIVE PRODUCTION LOTS SHOWING THAT SUCH SPECIFICATIONS CAN BE MET SHOULD ALSO BE FURNISHED.

B. USAGE - - DETAILS OF PROPOSED FOOD-PACKAGING USAGE: INDIVIDUAL FOODS OR TYPES OF FOODS (SPECIFIC EXAMPLES) TO BE PACKAGED, MAXIMUM TEMPERATURE OF PACKAGING, MAXIMUM TEMPERATURE AND TIME OF STORAGE, MAXIMUM TEMPERATURE AND TIME OF COOKING IF FOOD IS TO BE SUBSEQUENTLY COOKED OR PROCESSED IN THE PACKAGE OR CONTAINER, MINIMUM SIZE OF PACKAGE (WEIGHT OF FOOD) TO BE USED, AND AREA AND MIL THICKNESS (INCLUDING WEIGHT) OF FILM OR OTHER CONTAINER SUCH AS A BOTTLE OR COATING EXPOSED TO FOOD IN THE MINIMUM SIZE PACKAGE. SIMILAR DETAILS OF FOOD PROCESSING EQUIPMENT USAGE.

C. INTENDED TECHNICAL EFFECT - - THE INTENDED EFFECT OF EACH SUBSTANCE IN THE FOOD-CONTACT SURFACE IS TO BE DESCRIBED WITH ACCOMPANYING DATA SHOWING THE INTENDED EFFECT IS ACCOMPLISHED; AND IF THE MIGRATION TO FOOD IS A FUNCTION OF THE QUANTITY OF THE SUBSTANCE PRESENT, DATA SHOULD BE FURNISHED SHOWING THAT THE PROPOSED LEVEL OF THE SUBSTANCE IN THE SURFACE IS IN AN AMOUNT NOT MORE THAN THAT REASONABLY REQUIRED TO ACCOMPLISH THE INTENDED EFFECT. IF THE FOOD ADDITIVE IS A COMPONENT OF A SINGLE SERVICE (ONE TIME USE) FOOD-PACKAGING CONTAINER, INFORMATION SHOULD BE FURNISHED TO SHOW WHETHER THE CONTAINER IS LIKELY TO BE REUSED BY THE CONSUMER FOR HOLDING OR STORING FOOD.

SAMPLES. TO BE FURNISHED ONLY ON REQUEST. IN ORDER TO ASSIST US IN EVALUATING THE PROPOSED USE, WE SHALL USUALLY REQUIRE SAMPLES OF THE FOOD-PACKAGING MATERIALS, OR COATED PANELS OR OTHER SUITABLE SPECIMENS OF FOOD-PROCESSING EQUIPMENT, REFLECTING THE PROPOSED USAGE.

D. QUANTITY OF THE INDIRECT ADDITIVE IN FOOD:

1. EXTRACTION DATA TO SHOW THE LIKELY DEGREE OF MIGRATION TO FOOD OF ALL COMPONENTS OF THE FINISHED FORMULATED PACKAGING MATERIAL OR THE FOOD-PROCESSING EQUIPMENT UNDER THE MOST SEVERE CONDITIONS AS WELL AS UNDER THE USUAL CONDITIONS OF PROPOSED USAGE. THE MAXIMUM AS WELL AS THE AVERAGE QUANTITY OF THE FOOD ADDITIVE TO BE EXPECTED IN INDIVIDUAL FOODS OR TYPES OF FOODS AND THE TOTAL DAILY DIET OF THE CONSUMER IS TO BE ESTIMATED AND THE BASIS FOR THE ESTIMATION IS TO BE DESCRIBED IN DETAIL, INCLUDING ANY ASSUMPTIONS MADE AND THE ARITHMETICAL COMPUTATIONS. TESTS ARE TO BE PERFORMED ON TEST SPECIMENS (FILMS, BOTTLES, PANELS, CANS, OR OTHER SUITABLE SAMPLES) REFLECTING THE INTENDED CONDITIONS OF USE. THE MAXIMUM QUANTITY OF ANY COMPONENT, INCLUDING THE MAXIMUM THICKNESS OF THE FILM OR CONTAINER (BOTTLE), THAT IS LIKELY TO BE USED IN PRACTICE SHOULD BE IN THE TEST SPECIMENS. ALL FAMILIES OF POLYMERS THAT ARE TO BE USED WITH A NEW ADJUVANT SHOULD BE TESTED. IF THE ADJUVANT IS A CATALYST, AN EXPLANATION OF ITS NATURE AND FATE IN THE PROCESSED ARTICLE SHOULD BE FURNISHED.

COMPREHENSIVE EXTRACTION DATA ARE USUALLY REQUIRED FOR FOOD-PACKAGING MATERIALS TO SHOW WHETHER THE PRACTICABLE TESTS AND LIMITATIONS OF SEC. 121.2514 OR 121.2526, OR ONES SIMILAR THERETO, ARE ADEQUATE FOR THE NEW SUBSTANCE, OR WHETHER OTHER END-TESTS AND LIMITATIONSS ARE REQUIRED TO PROTECT THE PUBLIC HEALTH. FOR PURPOSES OF ADEQUATELY CHARACTERIZING THE FOOD-CONTACT SURFACE TO BE USED FOR AQUEOUS OR FATTY FOODS, EXTRACTION TESTS MUST INCLUDE ALL THE FOLLOWING SOLVENTS EVEN THOUGH USAGE IS TO BE LIMITED TO ONLY ONE OF THESE TWO MAJOR TYPES OF FOOD: DISTILLED WATER, 3% ACETIC ACID, 50% ETHYL ALCOHOL, AND HEPTANE. THE EXPOSURE IS TO BE MADE AT 120° F IN EACH CASE UNTIL THE MAXIMUM EXTRACTABILITY (EQUILIBRIUM) IS REACHED AS GAUGED BY AT LEAST THREE PERIODIC DETERMINATIONS. FOR AQUEOUS SOLVENTS, THE EXPOSURE TIME MUST TOTAL AT LEAST 72 HOURS AND FOR HEPTANE AT LEAST 6 HOURS. AS A GENERAL RULE, USE 2 ML SOLVENT PER SQUARE INCH OF AREA. SEE THE ASTM-AOAC METHOD, SEC. 7.034-7.039, METHODS OF ANALYSIS, A.O.A.C., TENTH ED., 1965. IF ONE OR MORE OF THE CONDITIONS OF USE (TABLE 2) AND THE LIMITATIONS TOGETHER WITH THE END-TESTS

IN SEC. 121.2526 OF THE FOOD ADDITIVE REGULATIONS ARE APPLICABLE TO THE USAGE PROPOSED, DATA MUST BE PROVIDED TO SHOW THE EXTRACTABILITY RELATIONSHIP BETWEEN THE EXPOSURE CONDITIONS OF TIME AND TEMPERATURE IN TABLE 2 REFLECTING THE MOST SEVERE CONDITIONS OF USAGE SOUGHT AND THE EXPOSURE CONDITIONS UNDER WHICH THE TEST IS CARRIED TO EQUILIBRIUM AT THE SAME TEMPERATURE. IF THE LIMITATIONS AND END-TESTS OF SEC. 121.2514 OR 121.2526 ARE PROPOSED, DATA REFLECTING SAMPLES FROM REPRESENTATIVE PRODUCTION LOTS SHOULD BE FURNISHED SHOWING THAT THESE LIMITATIONS CAN BE MET.

FOR FOOD PROCESSING AND HANDLING EQUIPMENT AND OTHER REPEATED USE ARTICLES THE DATA MUST SHOW THE LIKELY LEVEL OF MIGRATORY ADDITIVES CONTRIBUTED TO FOOD DURING THE FIRST USE OF THE ARTICLES AND THE LEVEL WHICH WILL LIKELY BE ADDED DURING THEIR SUBSEQUENT USE. IF THE END-TEST AND LIMITATIONS OF 121.2562 ARE PROPOSED, DATA REFLECTING SAMPLES FROM REPRESENTATIVE PRODUCTION LOTS SHOULD BE FURNISHED SHOWING THAT THESE LIMITATIONS CAN BE MET.

FOR USAGE IN CONTACT WITH CERTAIN FOODS, IT IS OFTEN DESIRABLE AND DEPENDING UPON THE EXTRACTABILITY DATA REFLECTING SIMULATED FOOD SOLVENTS, IT MAY BE NECESSARY TO DETERMINE THE EXTRACTIBILITY RELATIONSHIP BETWEEN THE SOLVENTS AND FOODS SUCH AS EDIBLE OIL, MILK, ETC. SINCE ANALYTICAL DIFFICULTIES ARE OFTEN ENCOUNTERED HERE, IT IS USUALLY ADVISABLE TO CONSULT WITH FDA AS TO WHETHER THESE EXTRACTABILITY RELATIONSHIP DATA ARE NEEDED.

AS A MINIMUM REQUIREMENT, ALL EXTRACTS USING FOOD SIMULANTS MUST BE CHARACTERIZED BY DETERMINING THE TOTAL NON-VOLATILE EXTRACTIVES AND BY SHOWING THE DISTRIBUTION BETWEEN THE ORGANIC AND INORGANIC FRACTIONS (SEE REGULATION 121.2526 FOR METHOD). IT MAY ALSO BE NECESSARY TO ANALYZE THE EXTRACTS FOR THE SPECIFIC FOOD ADDITIVES INVOLVED, DEPENDING UPON THE CIRCUMSTANCES. DETAILS OF THE ANALYTICAL PROCEDURES EMPLOYED MUST BE FURNISHED. IF COMPUTATIONS SHOW THAT NO MORE THAN 0.01 PPM OF A SUBSTANCE WOULD BE ADDED TO A FOOD ASSUMING IT ALL MIGRATED, THE EXTRACTS USUALLY NEED NOT BE TESTED FOR SUCH SUBSTANCE. IF NONE IS FOUND IN THE EXTRACTS, THE SENSITIVITY OF THE METHOD EMPLOYED MUST BE ADEQUATELY VALIDATED.

2. ABRASION DATA. FOR DRY FOODS SUCH AS BULK GRAIN. FLOUR, SALT, ETC., IN CONTACT WITH COATED SURFACES, OBTAIN ABRASION DATA USING THE MOST ABRASIVE FOOD CONCERNED OR AN ACCEPTABLE SUBSTITUTE. METHOD 6191 IN FEDERAL TEST METHOD STANDARD NO. 141 IS USUALLY ACCEPTABLE. IT MAY BE POSSIBLE, IN SOME INSTANCES, TO INCORPORATE A SUITABLE TRACER IN THE COATING FOR WHICH A SENSITIVE ANALYTICAL METHOD IS AVAILABLE. ALSO, INCLUDE PERFORMANCE DATA SHOWING THE COATING'S EXPECTED LIFE AND ITS RESISTANCE TO FLAKING OR PEELING.

3. END-TEST AND USUAGE SPECIFICATIONS FOR NON-FOOD ARTICLES TO ASSURE THAT THE PROPOSED USAGE IS SAFE. WHEN NECESSARY THE PETITIONER SHOULD PROPOSE MEANINGFUL SPECIFICATIONS FOR THE PURPOSE OF LIMITING TO SAFE AMOUNTS THE MIGRATION TO FOOD OF COMPONENTS OF THE FOOD-CONTACT SURFACE OF THE FINISHED NON-FOOD ARTICLE UNDER ITS PROPOSED CONDITIONS OF USE. THE END-TESTS FOR CHECKING SUCH SPECIFICATIONS SHOULD BE DESCRIBED IN DETAIL AND SHOWN TO BE VALID AND REPRODUCIBLE. DATA REFLECTING SAMPLES FROM REPRESENTATIVE PRODUCTION LOTS SHOULD BE FURNISHED SHOWING THAT THE SPECIFICATIONS CAN BE MET.

4. RESULTS OF FOOD TEST PACKS. ANY DATA OBTAINED IN EVALUATING THE UTILITY OR ACCEPTABILITY OF A PACKAGING MATERIAL OR OTHER NON-FOOD ARTICLE SHOULD BE INCLUDED IN THE PETITION SUBMITTED.

E. METHODOLOGY - - METHODS USEFUL IN CHECKING ON COMPLIANCE WITH THE REGULATION SOUGHT SHOULD BE FURNISHED AND IDENTIFIED AS SUCH. SEE D ABOVE.

III. PROTOCOL FOR RADIATION AND RADIATION SOURCES

A. IDENTITY:

1. RADIATION AND RADIATION SOURCE PROPOSED: A. IF AN ISOTOPE, IDENTIFY IT, AND DESCRIBE THE TYPE OF ENCAPSULATION USED; B. IF A MACHINE SOURCE, DESCRIBE IT.

2. ENGINEERING DATA PROVIDING COMPLETE INFORMATION ON THE GEOMETRY OF THE RADIATING MECHANISM, INCLUDING THE SPEED OF MOVEMENT BY THE RADIATING HEAD, THE RADIOISOTOPE, AND THE NUMBER OF CURIES IN THE SOURCE USED (IF ISOTOPES), THE VOLTAGE AND AMPERAGE USED (IF MACHINE), AND THE TOTAL TIME OF EXPOSURE. A STATEMENT OF THE RADIATION FLUX CALCULATED THEREFROM SHOULD BE INCLUDED.

3. DATA PROVIDING COMPLETE INFORMATION ON THE MEANS TO BE USED TO CONTROL THE EXPOSURE: A. IN THE CASE OF MACHINES, DATA SHOWING THE SENSITIVITY OF THE MEANS OF CONTROLLING THE POWER SOURCES, AND THE WAY IN WHICH RECORDERS ARE COUPLED TO PRODUCE RECORDS OF THE OPERATING VOLTAGES AND AMPERAGES; B. IN THE CASE OF ISOTOPES AND MACHINES, DESCRIBE THE NATURE OF THE DOSIMETER AND THE FREQUENCY OF THE DOSIMETRY AND FURNISH DATA SHOWING THE DOSIMETRY AND PHANTOMS TO BE USED, INCLUDING THOSE WHICH SHOW THE DOSIMETRY READINGS WILL ADEQUATELY REFLECT THE DOSE ABSORBED BY THE FOOD DURING EXPOSURE.

B. USE - - THIS SECTION SHOULD INCLUDE INFORMATION ON THE DOSE RANGES TO BE USED AND THE PURPOSE FOR WHICH THE RADIATION IS PROPOSED, TOGETHER WITH ALL DIRECTIONS, RECOMMENDATIONS, AND SUGGESTIONS REGARDING THE PROPOSED USE. THIS SECTION SHOULD ALSO INCLUDE SPECIMENS OF LABELING TO BE USED ON THE RADIATION SOURCES AND ANY LABELING TO BE USED ON THE TREATED FOOD.

C. TECHNICAL EFFECT:

1. EXPERIMENTAL DATA SHOULD BE SUBMITTED SHOWING THAT THE RADIATION DOSE PROPOSED ACCOMPLISHES THE INTENDED TECHNICAL EFFECT AND DOES NOT EXCEED THE AMOUNT REASONABLY REQUIRED TO ACCOMPLISH THE INTENDED EFFECT.

2. INFORMATION SHOULD BE INCLUDED SHOWING THAT THERE IS NO INDUCED RADIOACTIVITY IN THE FOOD OR PACKAGING MATERIAL. THIS CAN INCLUDE A THEORETICAL DISCUSSION BUT SOME ACTUAL EXPERIMENTATION DATA SHOULD BE PROVIDED TO SUPPORT THE THEORY ADVANCED. IF DIFFERENT RADIATION FLUXES ARE TO BE USED, THOSE MATERIALS SUBJECT TO THE HIGHEST FLUX AND DOSE CONTEMPLATED SHOULD BE SELECTED FOR TESTING FOR INDUCED RADIOACTIVITY. A DESCRIPTION OF THE METHODOLOGY AND THE SENSITIVITY OF THE METHODS USED TO ESTABLISH THE ABSENCE OF INDUCED RADIOACTIVITY IN THE TREATED FOODS OR PACKAGING MATERIAL SHOULD BE FURNISHED.

3. DATA SHOULD BE PROVIDED TO ESTABLISH THE EXTENT TO WHICH THE NUTRITIVE COMPOSITION OF THE IRRADIATED FOOD HAS BEEN ALTERED BY EXPOSURE OF THE FOOD TO THE HIGHEST DOSE AND UNDER THE HIGHEST FLUX EXPECTED. IF ANY SUCH CHANGES ARE FELT TO BE INSIGNIFICANT, THESE SHOULD BE SO DESIGNATED AND THE REASONS DETAILED FOR THEIR CLAIMED INSIGNIFICANCE. THE METHODOLOGY EMPLOYED SHOULD BE FULLY DESCRIBED.

4. DATA SHOULD BE PROVIDED TO ESTABLISH THAT THE IRRADIATED FOOD HAS NOT BEEN SIGNIFICANTLY ALTERED IN ORGANOLEPTIC OR OTHER PHYSICAL CHARACTERISTICS SO AS TO RENDER THE MATERIAL OTHERWISE UNFIT FOR FOOD. WHERE A FRESH FOOD IS ORDINARILY STORED FOR A PERIOD OF TIME AT PARTICULAR TEMPERATURES, DATA SHOULD BE INCLUDED REFLECTING THE RESULTS WHEN THE IRRADIATED FOOD IS APPROPRIATELY STORED AND/OR SHIPPED.

D. METHODS --- (SEE C).

(Story continued from Page 14)

Petition in the area of chemistry and technology. When a Petitioner omits any of the data and information suggested by the guidelines or substitutes other types of data and information for those suggested by the guidelines, he should clearly explain the reason for the omission or how such substituted data and information fulfill the legal requirements of the regulations.

"A general summary of the Petition should be supplied by the Petitioner. Among other things it should contain a statement with respect to the quantity of the food additive in individual foods or classes of foods, under the proposed conditions of use, and the maximum as well as the average quantity to be expected in the total daily diet of the consumer; and a statement with respect to the margin of safety provided by the animal feeding studies. The clearance sought should be included and specifically stated."

FDA-ers say the guidelines represent additions to the 1959 Ramsey document of material which has been disclosed over the years in papers, speeches, and in correspondence with industry.

Protocols are included for direct food additives, indirect additives, and irradiation. Veterinary drugs and feed additives are not included, since they are now handled in FDA's Bureau of Veterinary Medicine, rather than in the Petitions Control Branch of the Bureau of Science.

Washington Attorney Jerome H. Heckman, in a speech at last week's American Chemical Society meeting in New York, praised Ramsey and FDA Associate Commissioner Kirk for inspiring th new guid lines. He said, "Although industry will certainly take exception to some of the requirements the 'Guidelines' set