

FDA To Report Inspectional Findings to Management

Manufacturers will get more information on deficiencies found in their plants by Federal inspectors under a program started March 1 by the Food and Drug Administration.

"Significant adverse conditions or practices" reported by FDA inspectors during plant visits are to be forwarded to company officials by certified mail approximately three weeks after an inspection.

The summaries will not "minimize, overstate, or rationalize serious conditions," but relate "the facts with a minimum of qualification."

The program is being initiated in an effort to provide an additional opportunity to firms to correct shortcomings within their plants. Industry spokesmen have told the Agency that inspectors' findings would provide guidance in improving manufacturing practices.

Companies will be told in each letter, however, that the report "is not intended to imply that the FDA will, or will not, recommend any legal or criminal action" on the basis of an inspector's findings.

When food samples are collected in a plant and analyzed for filth, District Offices will send the results along with the letter if they are available in time. If not, the report of the analysis will be sent later.

When other Federal or State agencies are involved, they will also receive copies of letters sent to companies, the FDA said.

• New Products

Two new infrared spectrophotometers—the IR-18 and IR-20—have just been introduced by BECKMAN INSTRUMENTS, INC., Fullerton, Calif. The IR-20's wide 4000 to 250 cm^{-1} range extends into the far infrared region and is well suited for both organic and inorganic studies. The lower-priced IR-18 differs from the IR-20 only in its narrower 4000 to 600 cm^{-1} range. Special features include seven slit programs, variable period control, and nine scanning speeds for maximum versatility. Fastest scanning speed is five minutes for the IR-18, six minutes for the IR-20. The double-beam 100% line on both instruments is flat to within $\pm 1\%$. Percent transmittance accuracy is $\pm 1\%$ in the double-beam mode of operation and $\pm 0.5\%$ in the single-beam mode.

Two new concentration converters have just been introduced by BECKMAN INSTRUMENTS, INC., Fullerton, Calif. Designed primarily for use with fluorometers, colorimeters, and infrared, ultraviolet, and atomic absorption spectrophotometers, the converters automatically calculate concentration, absorbance, or percent transmission. Both converters will accept analog signals from any instrument capable of 100 mv output. One model converts the data to digital form for display or printout. Both models can plot out results on a potentiometric recorder.

NESTER/FAUST MFG. CORP., Newark, Del., has announced the development of an auto annular spinning band distillation system that provides easier operation, even for the uninitiated user, product purity up to 99.95+ % and fast equilibration time. The system includes an adiabatic annular distilling column, integrated automatic reflux ratio control, automatic temperature control for pot flask, integrated stroboscope for accurate motor speed adjustment, dual range (0 to 300C) pyrometer for pot and head and a safety deviation alarm device. The still is mounted to a protective support module while all controls are centered on a remote control console. The distillation system obtains very high rectification with estimated plates in the range of 125 to 200.

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demonstrated in rat cells, whereas these activities could not be shown in fat cells from human omental and subcutaneous tissue. The findings for human cells are attributed to changes in cellular activity during preparation.

PLACENTAL TRANSFER OF CHOLESTEROL-4- ^{14}C INTO RABBIT AND GUINEA PIG FETUS. W. E. Connor and D. S. Lin (Cardiovascular Res. Labs., Dept. of Int. Med. Univ. of Iowa College of Med., Iowa City, Iowa 52240). *J. Lipid Res.* 8, 558-64 (1967). A tracer dose of cholesterol-4- ^{14}C was given daily in the diet of six pregnant guinea pigs to establish an isotopic steady state. At the time of parturition, maternal and fetal blood and fetal tissues were collected and analyzed for cholesterol content and cholesterol specific activity. A comparison of these specific activities in neonatal and maternal serum indicated that about 22% of the fetal serum cholesterol was transferred from maternal blood. In the newborn, tissues generally had the same cholesterol specific activity as serum. Brain tissue was an exception in having a specific activity only 8.4% of that of serum. Dietary cholesterol did not increase serum cholesterol levels in the newborn but did increase the percentage of fetal cholesterol derived from the maternal circulation. The rapid transfer of cholesterol-4- ^{14}C across the placenta was indicated by the appearance of this isotope in the newborn 2 days after its administration to pregnant rabbits. A considerable amount of the cholesterol content of newborn guinea pigs and rabbits originated from the maternal blood.

INCREASE IN CELL LIPID AND CYTOPLASMIC PARTICLES IN MAMMALIAN CELLS CULTURED AT REDUCED pH. C. C. Mackenzie, Julia B. Mackenzie, and O. K. Reiss (Dept. of Biochem., Univ. of Colorado School of Med., and the Webb-Waring Inst. for Med. Res., Denver, Colorado 80220). *J. Lipid Res.* 8, 642-5 (1967). The hydrogen ion concentration of the medium has been shown to exert a regulatory effect on the lipid content of cultured mammalian cells. Reduction of the pH of the medium from 7.4 to 6.9 causes a significant increase in cell lipid, relative to cell protein, within 2-3 days. Triglycerides are increased twofold and account for 75% of the additional lipid. Polar lipids, on the other hand, remain nearly constant in concentration. Concurrent with the increase in lipid, particles with an average diameter of 1 μ appear in the cytoplasm. Because the density of these particles is low, ultracentrifugation of the cell homogenate separates the particles completely from the other subcellular structures. The amount of lipid in the particle fraction is approximately equal to the increase in total cell lipid. As shown by silicic acid column chromatography, the particle lipid contains about 75% triglycerides, 15% diglycerides plus an unknown substance, and smaller amounts of material in the monoglyceride and sterol ester-hydrocarbon fractions. The quantitative results indicate that the lipid accumulated at low pH is assembled into discrete cytoplasmic particles.

INTERACTION OF PHOSPHOLIPID-METAL COMPLEXES WITH WATER-SOLUBLE WHEAT PROTEIN. J. G. Fullington (Western Reg. Res. Lab., Agr. Res. Service, U. S. Dept. of Agr., Albany, Calif. 94710). *J. Lipid Res.* 8, 609-14 (1967). Insoluble lipid-protein complexes are formed in the presence of Ni (II), Ca (II), or Mg (II) by specific components of the water-soluble proteins of wheat flour and either triphosphoinositide or phosphatidyl serine. The pattern of protein species bound by the lipid-metal complex is dependent upon the metal and the phospholipid used. A group of proteins, containing carbohydrate, may be solubilized and recovered by washing the precipitate with acidic chloroform-methanol-water. Analyses of reactive and nonreactive protein species have shown no differences which clearly account for their behavior. Methylation of protein increases binding to lipid; acetylation decreases the interaction. Weak interaction has been observed between certain components of flour proteins and phospholipid in the absence of metal ions, but the components differ from those bound in the presence of metal ions. It is suggested that properly oriented groups of the protein molecules are chelating onto available coordination positions of metal ions already bound to phospholipid.

COMPOSITION OF MYELIN FROM PERIPHERAL AND CENTRAL NERVOUS SYSTEMS OF THE SQUIRREL MONKEY. L. A. Horrocks (Lab. of Neurochem., Cleveland Psychiatric Inst., Cleveland, Ohio 44109). *J. Lipid Res.* 8, 569-76 (1967). Myelin was prepared from the brachial plexus and cervical spinal cord of adult