DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Implementation of the National Occupational Research Agenda (NORA), RFA OH–99–002, Program Area #6 Special Populations at Risk/Aging Workforce

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Implementation of the National Occupational Research Agenda (NORA), RFA OH–99–002, Program Area #6 Special Populations at Risk/Aging Workforce.

Times and Dates:

1 p.m.–1:30 p.m., August 4, 1999 (Open)
1:30 p.m.–6 p.m., August 4, 1999 (Closed)

Place: Embassy Suites Hotel, 1900 Diagonal Rd., Alexandria, Va. 22134.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to the NORA RFA OH–99–002.

Contact Person For More Information: Michael J. Galvin, Jr., Ph.D., Health Scientist Administrator, Office of Extramural Coordination and Special Projects, NIOSH, CDC, 1600 Clifton Rd., Atlanta, Ga. 30333. Telephone 404/639–3525, e-mail mtg3@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–18550 Filed 7–16–99; 1:49 pm]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2336]

Holliday Pigments, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Holliday Pigments, Ltd. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of manganese ammonium pyrophosphate (C.I. Pigment Violet 16) as a colorant for all polymers intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by August 20, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4670) has been filed by Holliday Pigments, Ltd., Morley St., Kingston upon Hull, HU8 8DN ENGLAND. The petition proposes to amend the food additive regulations in §178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of manganese ammonium pyrophosphate (C.I. Pigment Violet 16) as a colorant for all polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 20, 1999, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 25, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–18582 Filed 7–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1458]

Enforcement Policy: Electronic Records; Electronic Signatures—Compliance Policy Guide; Guidance for FDA Personnel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new Compliance Policy Guide (CPG) section 160.850 entitled ''Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures.'' This CPG is intended to represent the agency's current thinking on how to comply with the regulations for electronic records and electronic signatures. It also provides that agency decisions on whether or not to pursue regulatory actions will be based on a case-by-case evaluation. The text of the CPG is included in this document.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of CPG section 160.850 entitled ''Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Send two self-addressed

adhesive labels to assist that office in processing your requests. Written comments should be identified with the docket number found in brackets in the heading of this document and should be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A copy of the CPG is available on FDA's website at ''http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/default.htm''. Scroll down the CPG page to locate section 160.850.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–0425.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a new CPG section 160.850 entitled ''Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures.'' The CPG is an update to the Compliance Policy Guides Manual (August 1996 ed.). It is a new CPG and will be included in the next printing of the Compliance Policy Guides Manual. The CPG is intended for FDA personnel and is available electronically to the public. See the **ADDRESSES** section for electronic access to the CPG. The CPG is a level 2 guidance which is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

The text of the CPG follows:

Section 160.850

Title: Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17)

Background:

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). This is a new Compliance Policy Guidance (CPG) and will be included in the next printing of the Compliance Policy Guidances Manual. The CPG is intended for Food and Drug Administration (FDA) personnel and is available electronically to the public. This guidance document represents the agency's current thinking on how to comply with 21 CFR Part 11, ''Electronic Records; Electronic Signatures'' and provides that agency decisions on whether or not to pursue regulatory actions will be based on a case by case evaluation. The CPG does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

In the **Federal Register** of March 20, 1997 at 62 FR 13430, FDA issued a notice of final rulemaking for 21 CFR, Part 11, Electronic Records; Electronic Signatures. The rule went into effect on August 20, 1997. Part 11 is intended to create criteria for electronic recordkeeping technologies while preserving the agency's ability to protect and promote the public health (e.g., by facilitating timely review and approval of safe and effective new medical products, conducting efficient audits of required records, and when necessary pursuing regulatory actions). Part 11 applies to all FDA program areas, but does not mandate electronic recordkeeping. Part 11 describes the technical and procedural requirements that must be met if a person chooses to maintain records electronically and use electronic signatures. Part 11 applies to those records required by an FDA predicate rule and to signatures required by an FDA predicate rule, as well as signatures that are not required, but appear in required records.

Part 11 was developed in concert with industry over a period of six years. Virtually all of the rule's requirements had been suggested by industry comments to a July 21, 1992 Advance Notice of Proposed Rulemaking (at 57 FR 32185). In response to comments to an August 31, 1994 Proposed Rule (at 59 FR 45160), the agency refined and reduced many of the proposed requirements in order to minimize the burden of compliance. The final rule's provisions are consistent with an emerging body of federal and state law as well as commercial standards and practices. Certain older electronic systems may not have been in full compliance with Part 11 by August 20, 1997, and modification to these so called ''legacy systems'' may take more time. As explained in the preamble to the final 1rule, Part 11 does not grandfather legacy systems and FDA expects that firms using legacy systems will begin taking steps to achieve full compliance.

Policy:

When persons are not fully compliant with Part 11, decisions on whether or not to pursue regulatory actions will be based on a case by case evaluation, which may include the following:

Nature and extent of Part 11 deviation(s). FDA will consider Part 11 deviations to be more significant if those deviations are numerous, if the deviations make it difficult for the agency to audit or interpret data, or if the deviations undermine the integrity of the data or the electronic system. For example, FDA expects that firms will use file formats that permit the agency to make accurate and complete copies in both human readable and electronic form of audited electronic records. Similarly, FDA would have little confidence in data from firms that do not hold their employees accountable and responsible for actions taken under their electronic signatures.

Effect on product quality and data integrity. For example, FDA would consider the absence of an audit trail to be highly significant when there are data discrepancies and when individuals deny responsibility for record entries. Similarly, lack of operational system checks to enforce event sequencing would be significant if an operator's ability to deviate from the prescribed order of manufacturing steps results in an adulterated or misbranded product.

Adequacy and timeliness of planned corrective measures. Firms should have a reasonable timetable for promptly modifying any systems not in compliance (including legacy systems) to make them Part 11 compliant, and should be able to demonstrate progress in implementing their timetable. FDA expects that Part 11 requirements for procedural controls will already be in place. FDA recognizes that technology based controls may take longer to install in older systems.

Compliance history of the establishment, especially with respect to data integrity. FDA will consider Part 11 deviations to be more significant if a firm has a history of Part 11 violations or of inadequate or unreliable recordkeeping. Until firms attain full compliance with Part 11, FDA investigators will exercise greater vigilance to detect inconsistencies, unauthorized modifications, poor attributability, and any other problems associated with failure to comply with Part 11.

Regulatory Action Guidance:

Program monitors and center compliance offices should be consulted prior to recommending regulatory action. FDA will consider regulatory action with respect to Part 11 when the electronic records or electronic signatures are unacceptable substitutes for paper records or handwritten signatures, and that therefore, requirements of the applicable regulations (e.g., CGMP and GLP regulations) are not met. Regulatory citations should reference such predicate regulations in addition to Part 11. The following is an example of a regulatory citation for a violation of the device quality system regulations.

Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820.40, and failure to use authority checks to ensure that only authorized individuals can use the system and alter records, as required by 21 CFR 11.10(g). For example, engineering drawings for manufacturing equipment and devices are stored in AutoCAD form on a desktop computer. The storage device was not protected from unauthorized access and modification of the drawings.

Dated: July 1, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18581 Filed 7–20–99; 8:45 am]

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