Preparations (Version 2001 Catalog, page 3 of 34 at: *http://www9.who.int/vaccines/Biologicals/KAlph.pdf*)).

4. Ferguson, M., et al., ''Hepatitis A Immunoglobulin: an International Collaborative Study to Establish the Second International Standard,'' *Biologicals*, 28:233–240, 2000.

5. Devalle, S., V.S. de Paula, J.M. de Oliveira, et. al., ''Hepatitis A virus infection in hepatitis C Brazilian patients,'' *Journal of Infectious Diseases*, August, 47(2):125–128, 2003.

6. Koff, R.S., ''Risks associated with hepatitis A and hepatitis B in patients with hepatitis C,'' *Journal of Clinical Gastroenerology*, July, 33(1):20–26, 2001.

7. Vento, S., ''Fulminant hepatitis associated with hepatitis A virus superinfection in patients with chronic hepatitis C,'' *Journal of Viral Hepatitis*, May; 7 Suppl 1:7–8, 2000.

8. Stapleton, J.T., ''Host immune response to hepatitis A virus,'' *Journal of Infectious Diseases,* 171(S1):S9–S14, 1995.

9. Hollinger, F.B. and S.U. Emerson, ''Hepatitis A Virus,'' in D.M. Knipe et al., eds. *Fields Virology*, 4th ed. Lippincott Williams and Wilkins, Philadelphia, 799–840, 2001.

10. Brown, E.A., and J.T. Stapleton, ''Hepatitis A Virus'' in P.R. Murray et al., eds., Manual of Clinical Microbiology, 8th ed., ASM Press, Washington, DC, 1452–1463, 2003.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is proposed to be amended as follows:

PART 866–IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3310 is added to subpart D to read as follows:

§ 866.3310 Hepatitis A Virus (HAV) serological assays.

(a) *Identification*. Hepatitis A virus serological assays are devices that consist of antigens and antisera for the detection of hepatitis A virus-specific IgM, IgG, or total antibodies (IgM and IgG), in human serum or plasma. These devices are used for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis or for determining if an individual has been previously infected with hepatitis A virus. The detection of these antibodies aids in the clinical laboratory diagnosis of an acute or past infection by hepatitis A virus in conjunction with other clinical laboratory findings. These devices are not intended for screening blood or solid or soft tissue donors.

(b) *Classification*. Class II (special controls). The special control is ''Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus.'' See § 866.1(e) for the availability of this guidance document.

Dated: September 21, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–22009 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA65

Financial Crimes Enforcement Network; Amendment to the Bank Secrecy Act Regulations—Imposition of Special Measure Against First Merchant Bank OSH Ltd, Including Its Subsidiaries, FMB Finance Ltd, First Merchant International Inc, First Merchant Finance Ltd, and First Merchant Trust Ltd, as a Financial Institution of Primary Money Laundering Concern

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: On August 24, 2004, FinCEN requested public comment on a proposed rulemaking to impose a special measure against First Merchant Bank OSH Ltd as a financial institution of primary money laundering concern, pursuant to the authority contained in 31 U.S.C. 5318A of the Bank Secrecy Act. FinCEN is extending the comment period on the proposal until November 1, 2004. This action will allow interested persons additional time to analyze the issues and prepare their comments.

DATES: Written comments on the notice of proposed rulemaking (69 FR 51979) must be submitted on or before November 1, 2004.

ADDRESSES: You may submit comments, identified by RIN 1506–AA65, by any of the following methods:

- Federal e-rulemaking portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *regcomments@fincen.treas.gov.* Include RIN 1506–AA65 in the subject line of the message.
- Mail: FinCEN, P.O. Box 39, Vienna, VA 22183. Include RIN 1506–AA65 in the body of the text.

Instructions: It is preferable for comments to be submitted by electronic mail because paper mail in the Washington, DC, area may be delayed. Please submit comments by one method only. All submissions received must include the agency name and the Regulatory Information Number (RIN) for this proposed rulemaking. All comments received will be posted without change to *http://www.fincen.gov,* including any personal information provided. Comments may be inspected at FinCEN between 10 a.m. and 4 p.m., in the FinCEN reading room in Washington, DC. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 354–6400 (not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Office of Regulatory Programs, FinCEN, at (202) 354–6400 or Office of Chief Counsel, FinCEN, at (703) 905–3590 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: On August 24, 2004, FinCEN requested comment on a proposal to impose the special measure authorized by 31 U.S.C. 5318A(b)(5) against First Merchant Bank OSH Ltd, including its subsidiaries, FMB Finance Ltd, First Merchant International Inc, First Merchant Finance Ltd, and First Merchant Trust Ltd. That special measure authorizes the prohibition of the opening or maintaining of correspondent or payable-through accounts by any domestic financial institution or domestic financial agency for, or on behalf of, a foreign financial institution found to be of primary money laundering concern.

The proposal was published for a 30-day comment period, which closed September 23, 2004. In order to ensure that as many interested parties as possible have time to comment on the proposal, the comment period is being extended to November 1, 2004.

Dated: September 23, 2004.

William J. Fox,

Director, Financial Crimes Enforcement Network.

[FR Doc. 04–21879 Filed 9–29–04; 8:45 am]

BILLING CODE 4810–02–P