Dated: July 21, 1999.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–19084 Filed 7–26–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Workshop; The National Vaccine Program Office, National Vaccine Advisory Committee Announces the Following Workshop.

Name: Thimerasol in Vaccines.

Times and Dates: 9 a.m.–5 p.m., August 11, 1999, 9 a.m.–1 p.m., August 12, 1999.

Place: National Institutes of Health, Lister Hill Auditorium, Bethesda, Maryland.

Status: Open to the public, limited only by the space available.

Purpose: The agenda will include discussions on thimerasol in vaccines and its reduction and elimination from vaccines. Agenda items are subject to change as priorities dictate.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the National Institutes of Health by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each day either between 8 and 8:30 a.m. or 12:30 and 1 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured.

Contact Person for More Information: Alicia Postema, National Vaccine Program Office, CDC, 1600 Clifton Road, NE, M/S A–11, Atlanta, Georgia 30333, telephone 404/639–4450.

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 CDC and ATSDR.

Dated: July 20, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–19086 Filed 7–26–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–6000]

Memorandum of Understanding Between the Food and Drug Administration and the Federal Aviation Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Federal Aviation Administration (FAA). The purpose of the MOU is to act in cooperation to reduce the incidents of aircraft illumination by laser projections into navigable airspace.

DATES: The agreement became effective November 25, 1998.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldricks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–4692.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20. 108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

225-99-6000

MEMORANDUM OF UNDERSTANDING BETWEEN THE UNITED STATES DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION AND THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

This interagency Memorandum of Understanding (MOU) is between the U.S. Department of Health and Human Services, Food and Drug Administration (FDA), and the U.S. Department of Transportation, Federal Aviation Administration (FAA).

WHEREAS, it is a purpose of the FDA to regulate electronic products pursuant to the Radiation Control for Health and Safety Act of 1968, as amended, 21 U.S.C. §§360hh-ss. The FDA Center for Devices and Radiological Health (CDRH) establishes and carries out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation.

WHEREAS, it is a purpose of the FAA, Office of Airspace Management, to establish administrative policy, criteria, and procedures for managing the navigable airspace, and to regulate civil and military operations in that airspace in the interest of safety as provided in 49 U.S.C. Subtitle VII with designated responsibility to its FAA Regional Offices and, when necessary, its local FAA offices or facilities.

WHEREAS, laser projection into navigable airspace pose potential safety hazards to aviation in that such projections may have harmful or adverse effects on the vision of aircraft pilots, crewmembers, and passengers.

WHEREAS, FAA and FDA agree to act in cooperation to reduce the incidents of aircraft illumination by laser projections into navigable airspace.

NOW THEREFORE:

The FAA and the FDA have regulatory responsibilities concerning laser products that project into navigable airspace, including demonstration laser products such as laser light shows and displays, and other products used in scientific and research applications.

For their respective authorities, the agencies agree as follows:

I. Purpose and Scope

A. The purpose of this MOU is to coordinate existing FAA and FDA regulatory programs applicable to laser light shows and displays, as well as scientific or research operations, which may project laser light radiation into navigable airspace during any part of their operation. Regulatory programs include activities for evaluating the manufacture and production of laser products.

B. Laser products affected by this MOU include, but are not limited to: outdoor, unenclosed Class IIIb or IV laser light shows; permanent outdoor, unterminated laser displays; outdoor displays employing 'soft' diffusing objects such as smoke, clouds, water sprays, foliage, etc, which cannot provide well determined scattering effects; laser 'beacons'; and scientific, research, or other laser display configurations which could project lasers into navigable airspace.

II. Authority and Regulatory Program

A. FDA

FDA is responsible for establishing and carrying out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation.

FDA/CDRH

FDA/CDRH regulates electronic products under the Radiation Control for Health and Safety Act of 1968, which is incorporated into the Food, Drug, and Cosmetic Act (FDCA) at 21 U.S.C. §§360hh.

21 U.S.C. §360hh defines "electronic product radiation" and "electronic product" as follows:

(1) "The term 'electronic product radiation' means --

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or
(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;"

(2) "The term 'electronic product' means--

(A) any manufactured or assembled product which, when in operation,
(i) contains or acts as part of an electronic circuit and
(ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation."

21 U.S.C. §360kk provides:

"The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he/[she] determines that such standards are necessary for the protection of the public health and safety."

21 C.F.R. §5.10 delegates responsibility for the promulgation of performance standards to FDA.

Pursuant to 21 U.S.C §360kk, the FDA/CDRH promulgated the Federal laser product performance standard, 21 C.F.R. §1040.10 and §1040.11. This standard specifies certain performance, labeling, and information requirements suited to the degree of hazard that a laser product may present.

The terms "laser product" and "demonstration laser product" are defined in the laser product performance standard as follows:

> 21 C.F.R. §1040.10(b)(21) " 'Laser product' means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product."
>
> 21 C.F.R. §1040.10(b)(13) " 'Demonstration laser product ' means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition."

FDA/CDRH programs intended to ensure compliance of laser products and of the operations of laser product manufacturers with all applicable regulations include, but are not limited to the following:

1. Review of product reports to assure that the products are designed and manufactured to be compliant with the laser product performance standard;

2. Review of requests for variances to deviate from specific requirements of the laser product performance standard to assure that suitable alternate means of radiation protection are provided in lieu of meeting the specific requirements identified in the variance request;

3. Requirements for holders of approved variances to provide written notice to the FAA of any outdoor laser shows or displays. The notices are to be submitted 30 days in advance of the activity to the FAA regional office where the show is to occur;

4. Technical assistance to FAA as requested in the analysis of proposed display(s) or scientific/research operations and the development of policies; and

5. General enforcement activities such as routine and directed inspections, field tests, surveillance, compliance testing program disapproval's, variance withdrawals, recalls, warning letters, other adverse findings letters, and case actions such as injunction and civil penalties.

B. FAA

FAA is responsible for establishing administrative policy, criteria, and procedures for management of navigable airspace and for the protections of users of the National Airspace System (NAS). The FAA's authority is set forth in 49 U.S.C. Subtitle VII - Aviation Programs, Part A - Air Commerce and Safety.

The Administrator of the FAA may prescribe standards and issue orders as necessary to carry out the duties and powers assigned to him/[her]in 49 U.S.C. Subtitle VII. 49 U.S.C. §§106 (g) (A), 40113.

> 49 U.S.C.§40102(a) defines the following terms:
>
> 49 U.S.C. §40102(a)(6) " 'aircraft' means any contrivance invented, used, or designed to navigate, or fly in the air."
>
> 49 U.S.C. §40102(a)(9) " 'airport' means a landing area used regularly by for receiving or discharging passengers or cargo."

49 U.S.C. §40102(a)(20) " 'Federal airway' means a part of navigable airspace that the Administrator designates as a Federal airway" (e.g., Jet route or Victor airway).

49 U.S.C.§40102(a)(28) " 'landing area' means a place on land or water including an airport or intermediate landing field, used, or intended to be used, for the takeoff and landing of aircraft, even when facilities are not provided for sheltering, servicing, or repairing aircraft, or for receiving or discharging passengers or cargo."

49 U.S.C. §40102(a)(30) " 'navigable airspace' means airspace above the minimum altitudes of flight prescribed by regulations under this subpart and subpart III of this part, including airspace needed to ensure safety in the takeoff and landing of aircraft."

FAA Order (FAAO) 7400.2, Procedure for Handling Airspace Matters, prescribes policy, criteria, and procedures for management of navigable airspace.

FAAO 7400.2, Miscellaneous Procedures, specifically addresses Outdoor Laser Operations, and terms associated with laser activities.

The FAA conducts an aeronautical study of all proposals received for outdoor laser activities to determine the potential effect upon aircraft operations. The FAA aeronautical study is intended to ensure adequate protection of users of the NAS. Specific requirements of the aeronautical studies can be found in FAA Order 7400.2.

FAA activities associated with aeronautical studies include but are not limited to the following:

1. providing the expertise and knowledge of known airport locations, flight paths, and traffic patterns in the areas surrounding the site of the laser display which may be in use during the time of the display;

2. coordination with the military liaisons stationed in the region or locale of the show to include consideration of the effects on military flight operations which may occur in the area of the display during the time of its operation;

3. review of proposed laser light show operations producing projections into airspace in accordance with FAAO 7400.2;

4. issuing the appropriate determination letter (OBJECTION or NON-OBJECTION, including any applicable conditions in the latter case) to the laser light show proponent; and

5. discussing the reasons for an objection with a laser light show proponent and negotiating possible suitable modifications or limitations of the proposed show with the goal of resolving the reasons for objection.

III. Elements of Coordination

A. Notifications of Proposed Outdoor Laser Light Shows

Variances from the FDA laser product performance standard for laser light shows and displays will contain a requirement to notify FAA in accordance with the effective FAAO 7400.2 and/or other FAA policy and guidance criteria for any laser light show or display which may project laser light into airspace at any time during its deployment (testing, installation, setup, rehearsals, and show operations.) An attachment to the variance will incorporate at least the content and processing parts of Miscellaneous Procedures of FAAO 7400.2.

When processing a variance request for a permanent (i.e., of indefinite duration at one particular location) outdoor display, FDA will confirm FAA notification and response prior to granting any variance for a display in an airspace area. As part of the process of deciding whether to grant the variance, FDA may also directly request advice from the FAA regional office concerning the possible effects of such a laser display on airspace usage.

B. Technical Analysis of Laser Shows or Displays

Upon request, the FDA will assist the FAA to the fullest extent possible with the technical analysis of proposed laser operations. This analysis shall include confirmation of an alternate nominal ocular hazard distance analysis provided by the proponent for pulsed laser operations. The FDA will also advise FAA concerning the adequacy of the hazard analyses and control measures submitted for proposed scientific/research laser operations in navigable airspace.

Upon request, the FAA will assist and advise the FDA concerning the nature of airspace usage in the vicinity of a proposed laser light show. This information may be requested, when considered relevant, as part of the process of review of a variance application to determine whether it is appropriate to grant the variance.

C. Support for Research to Determine Suitable Visual Impairment Limits

FAA and FDA will provide support to the fullest extent possible for a research program led by FAA in cooperation with FDA and other governmental or private agencies to check the suitability of the limits adopted in FAAO 7400.2 for protection against temporary visual impairments such as flashblindness, afterimage, glare, etc.

D. Notification of Aircraft Illumination Incidents

FAA in cooperation with FDA and other governmental or private agencies will develop an appropriate incident reporting system to help pilots or other crew members provide information on aircraft illumination incidents.

FAA will provide information concerning illumination incidents from lasers and other high intensity light sources to FDA as it is received or extracted from the data in the reporting system.

FDA will in turn alert FAA to any reports it may receive, in case the information wasn't reported in the above reporting system.

E. Coordination of Investigations

Upon request, FDA and FAA will assist each other, to the fullest extent possible, in the investigation of incidents or complaints involving aircraft illuminations and the effects on the pilots, crewmembers, or passengers. For purposes of this MOU, investigations will be considered to include inspections in response to incidents or events, as well as formal investigations initiated in accordance with each agency's internal procedures. During the term of this agreement, joint inspections or observer invitations can be requested or extended by either agency, when deemed necessary, to ensure that information obtained from an investigation is collected, shared, and acted upon in a timely and coordinated manner. Both agencies will make every reasonable effort to accommodate joint inspection or observer requests depending upon availability of personnel and current FDA or FAA priorities. Each agency will assign one or more persons to assure that investigations are coordinated in a manner that maximizes regulatory efficiency and minimizes duplication of effort. Each agency will promptly notify the other when there is a change in an assigned contact person.

F. Investigation Information Exchange

Both agencies agree to an exchange of information with respect to investigations. The purpose of these exchanges is to provide expert technical assistance to either agency and to assist either agency by reducing or eliminating any duplication of effort. The sharing of information between FDA and FAA will be exercised to the extent authorized by law, and by FAA and FDA directives, and regulations, and will be consistent with the missions of both agencies.

Both agencies recognize the need to protect trade secret, confidential commercial or financial, and confidential personal or medical information from public disclosure. However, the agencies believe that an exchange of data and information to the extent allowed by law is necessary to achieve the ends of this agreement. Therefore, to the extent allowed under 21 U.S.C. §§331(j), §360ee(d), nn(e), and 360j(c), 18 U.S.C. §1905, 5 U.S.C. §552a(b), and 21 C.F.R. pt 20, the agencies agree to exchange information such as outlined below.

If FDA provides FAA with trade secret information, there shall be an exchange of letters between the appropriate liaison officers in accordance with 21 C.F.R. §20.85. If a request calls for a disclosure determination regarding proprietary information such as a Freedom of Information Act request, response to a Congressional inquiry, or in cases where either agency must comply with various regulatory or public information responsibilities for any such information obtained from the other agency, that agency will be notified of the request. The notified agency will be responsible for making any needed contact with the submitter of the protected information and accept the responsibility for evaluating the submitter's comments prior to rendering the disclosure determination.

To preserve the right of maximum control over actual disclosure of its own records, each agency shall retain legal authority and the commensurate responsibility over disclosure of those documents provided to the other agency.

Upon request, FDA and FAA will:

a. provide each other copies of Establishment or Field Test Inspection Reports;

b. provide each other copies of all analytical data and correspondence of significance related to investigations or activities associated with an illumination incident or event;

c. provide each other copies of official legal or compliance actions taken against firms or variance holders of mutual interest; and

d. participate in meetings with regulated industry covering issues of mutual regulatory concern.

G. Product Report and Variance Request Information Exchange

To the extent practicable, the two agencies will share information concerning new laser light show or display technology or methods under development or review, including laser projection systems, lasers, aircraft avoidance technologies for use with laser displays, etc., for which regulations have not yet been developed, or is related to the mission of the other agency. Both agencies agree to exchange proprietary information in accordance with applicable regulations. If FDA provides FAA with trade secret information, there shall be an additional written agreement in the form of an exchange of letters between the appropriate liaison officers in accordance with 21 C.F.R. §20.85.

This information may include, but is not limited to:

a. the product reports covering the lasers, laser projection system, and the laser light show;

b. the variance request;

c. any related correspondence requesting additional information; and

d. product report supplements providing additional information.

H. Sharing of Other Information

FDA and FAA will offer each other the opportunity to comment on special notifications to laser light show product manufacturers, operators, variance holders, facility owners, etc. FDA and FAA will also offer each other the opportunity to comment on regulations, regulatory guides, or other communications that refer to activities, policies, or regulations of the other agency as appropriate. Either agency may request additional information when deemed necessary to complete its mission.

I. Advisory Committees

FAA and FDA will make the other agency aware of, and, to the extent possible, allow participation by a representative from the other agency in, any Advisory Committee which advises on issues related to the MOU (e.g., Society for Automotive Engineering, Flight Deck Hazards Safety Committee).

IV. Names and Addresses of Participating Agencies

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Federal Aviation Administration
800 Independence Avenue, S.W.
Washington, DC 20591

V. Liaison Officers

Each liaison officer will establish and maintain a call list of the names and current work and home phone numbers of responsible persons within his or her organization. These call lists will designate specific persons for day-to-day contact on matters related to the MOU. The lists will be exchanged between the liaison officers. The lists will be updated every six months or whenever a liaison officer's or day-to-day contact person's phone number changes.

Liaison officers are as follows:

A. For the Food and Drug Administration

Director, Office of Compliance, HFZ-300
Ms. Lillian Gill
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850
Telephone: (301) 594-4692

B. For the Federal Aviation Administration

Program Director, Office of Airspace Management, ATA-1
Mr. John S. Walker
Federal Aviation Administration
800 Independence Avenue, SW
Washington, DC 20591
Telephone: (202) 267-9205

VI. Annual Inter-Agency Meeting

The liaison officers shall meet at least annually to evaluate the activities related to the MOU and make reports to agency heads on its effectiveness. FDA and FAA will host the meeting on alternating years.

VII. Other Laws and Matters

Nothing in the Memorandum of Understanding shall be deemed to restrict, modify, or otherwise limit the application or enforcement of any laws of the United States with respect to matters specified herein, nor shall anything in the memorandum be construed as modifying the existing authority of either agency.

VIII. Effective Date, Modification and Termination of MOU

This MOU will take effect when it has been signed by the authorized representatives of FDA and FAA. It may be modified by mutual written consent or terminated by either agency upon a sixty (60) day advance written notice to the other agency. The agencies agree to evaluate the agreement every three (3) years, at which time either agency would have the option of renewing, modifying, or canceling the MOU.

APPROVED AND ACCEPTED FOR THE FEDERAL AVIATION ADMINISTRATION	APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION
BY Ronald E Myers	BY Lillian J. Gill
TITLE Director of Air Traffic, FAA	TITLE Director, Office of Compliance, CDRH/FDA
DATE November 25, 1998	DATE July 24, 1998

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