The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP AZ E5 Grand Canyon, AZ [Amended]

Valle Airport, AZ
(Lat. 35°39′02″ N, long. 112°08′53″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the airport beginning at the 020° bearing from the airport clockwise to the 190° bearing from the airport, and within a 6.4-mile radius of the airport beginning at the 190° bearing from the airport clockwise to the 020° bearing from the airport.

Issued in Des Moines, Washington, on June 24, 2022.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–13976 Filed 6–29–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2022–N–0794]

General and Plastic Surgery Devices; Reclassification of Optical Diagnostic Devices for Melanoma Detection and Electrical Impedance Spectrometers, To Be Renamed Computer-Aided Devices Which Provide Adjunctive Diagnostic Information About Lesions Suspicious for Melanoma

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing on its own initiative to reclassify optical diagnostic devices for melanoma detection and electrical impedance spectrometers, both of which are postamendments class III devices (product codes OYD and ONV, respectively), into class II (special controls), subject to premarket notification. FDA is also proposing a new device classification regulation with the name ''computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma,'' along with special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices. If finalized, this order will reclassify these devices from class III to class II and the submission of a premarket approval application (PMA) for these devices will no longer be required, and instead the submission of a premarket notification (510(k)) will be required.

DATES: Submit either electronic or written comments on the proposed order by August 29, 2022. Please see section X of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 29, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–0794 for ''General and Plastic Surgery Devices; Reclassification of Optical Diagnostic Devices for Melanoma Detection and Electrical Impedance Spectrometers, To Be Renamed Computer-Aided Devices Which Provide Adjunctive Diagnostic Information about Lesions Suspicious for Melanoma.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday Eastern Time, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Neil Ogden, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4612, Silver Spring, MD 20993, 301–796–6397, *neil.ogden@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the issue of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not in commercial distribution before May 28, 1976 (generally referred to as ''postamendments devices'') are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless, and until: (1) FDA reclassifies the device into class I or II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of the premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807, subpart E, of FDA's regulations (21 CFR part 807).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 388–391 (D.D.C. 1991)) or in light of changes in ''medical science'' (*Upjohn Co.* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the information to support reclassification must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.1985)).

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved.

In accordance with section 513(f)(3) of the FD&C Act, FDA is issuing this proposed order to reclassify optical diagnostic devices for melanoma detection and electrical impedance spectrometers, both of which are postamendments class III devices, into class II (special controls) subject to premarket notification, under a new device classification regulation with the name ''computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma.'' FDA believes the standard in section 513(a)(1)(B) of the FD&C Act is met as there is sufficient information to establish special controls, which, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of these devices.[1]

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Proposed amendment; proposed

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma and, therefore, the Agency does not intend to exempt this proposed class II device from the requirement for premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

II. Regulatory History of the Devices

Under section 513(f)(1) of the FD&C Act, optical diagnostic devices for melanoma detection and electrical impedance spectrometers are automatically classified into class III because they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and have not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently classified or reclassified into class II or class I. Therefore, they are subject to PMA requirements under section 515 of the FD&C Act (21 U.S.C. 360e).

On November 1, 2011, FDA approved a PMA for MELAFIND, the first optical diagnostic device for melanoma detection to obtain FDA premarket authorization (Refs. 1–5). MELAFIND is intended for use on clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma. FDA filed the PMA for MELAFIND (P090012) from MELA Sciences, Inc. on June 9, 2009. At a meeting on November 18, 2010, the FDA General and Plastic Surgery Devices Panel (the ''Panel'') reviewed the MELAFIND PMA (Ref. 6). Among other things, the Panel raised concerns regarding the potential use of MELAFIND by non-dermatologists and untrained operators, and regarding the risk that negative MELAFIND readings could lead to false negative diagnoses (*e.g.,* where no referral forward or biopsy is done based on a negative MELAFIND finding) (Ref. 7). By a vote of eight to seven (with one Panel member abstaining), the Panel voted that the benefits of the device for the proposed indications outweighed its risks for the proposed indications.

FDA subsequently approved the device for use by dermatologists choosing to obtain additional information for a decision to biopsy (and not for confirming a clinical diagnosis of melanoma), and for use only on certain types of lesions—for example, lesions with a diameter between 2 mm and 22 mm, that are accessible by the MELAFIND imager, and that are sufficiently pigmented, among other things (Ref. 8). FDA also imposed certain labeling requirements on the device, including a requirement that the labeling specify that device is for use only by physicians trained in the clinical diagnosis and management of skin cancer (*i.e.,* dermatologists) who have also successfully completed a training program in the appropriate use of the device. FDA required that the sponsor conduct a post-approval study. The study was terminated in 2016 when additional data were provided in support of the safety and effectiveness of the device.

On June 28, 2017, FDA approved a PMA for NEVISENSE, the first electrical impedance spectrometer to obtain FDA premarket authorization. NEVISENSE is indicated for use on cutaneous lesions with one or more clinical or historical characteristics of melanoma, when a dermatologist chooses to obtain additional information when considering biopsy. It is not for use on clinically obvious melanoma and is to be used as one element of the overall clinical assessment.

As of the date of issuance of this proposed order, fewer than 6 years have transpired since FDA's approval of PMA Supplement 11 for MELAFIND (P090012 S11) and the PMA and PMA supplements for NEVISENSE (PMA P150046 and P150046 S1–S4). Therefore, no information from these documents has been used in support of this proposed order to reclassify optical diagnostic devices for melanoma detection and electrical impedance spectrometers into class II (see section 520(h)(4) of the FD&C Act (21 U.S.C. 360j(h)(4))).

As of the date of issuance of this proposed order, there has been a single recall involving the MELAFIND device, and no recalls involving the NEVISENSE device. The MELAFIND recall was initiated by the firm in April 2015 due to the display of probability and histogram data on the device's user interface that was not covered by the device's approval. This recall was classified as class II and was terminated in May 2016. FDA has received no Medical Device Reports (MDRs) associated with optical diagnostic devices for melanoma detection or electrical impedance spectrometers.

As of the date of issuance of this proposed order, no other optical diagnostic devices for melanoma detection or electrical impedance spectrometers have been approved by FDA.

III. Device Description

Optical diagnostic devices for melanoma detection and electrical impedance spectrometers are postamendments devices classified into class III under section 513(f)(1) of the FD&C Act. An optical diagnostic device for melanoma detection is a prescription device for use in the detection of melanoma and high-grade lesions among atypical lesions in order to rule out melanoma, through the use of visible and infrared optical radiation to generate images of targeted atypical lesions. The device is a multispectral, non-invasive, and automated (objective) computer-vision system that classifies the image of a pigmented skin lesion based upon the degree of 3-dimensional morphological disorganization. It is intended for use on clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma.

An electrical impedance spectrometer is a prescription device used on cutaneous lesions with one or more clinical or historical characteristics of melanoma, when a dermatologist chooses to obtain additional information when considering biopsy. The device consists of a control unit and a disposable electrode, which is used to measure electrical impedance of skin lesions and provide an output called the electrical impedance spectroscopy score. An electrical impedance spectrometer is not for use on clinically obvious melanoma, and is to be used as one element of the overall clinical assessment. The output given by the device is to be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to biopsy.

FDA proposes to revise 21 CFR part 878 to create a new device classification regulation with the name ''computer-

order,'' rather than ''Proposed order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma.'' A computer-aided device which provides adjunctive diagnostic information about lesions suspicious for melanoma is a device that is used to aid in the decision-making process for melanoma detection. The device is intended for prescription use by a physician trained in the clinical diagnosis and management of skin cancer (*e.g.,* a dermatologist) on skin lesions with one or more clinical or historical characteristics of melanoma, and is based on a computer algorithm to analyze optical or other physical properties of a skin lesion. The algorithm returns a classification of the skin lesion regarding melanoma when a physician trained in the clinical diagnosis and management of skin cancer chooses to obtain additional information when considering biopsy. The device is not for use as a stand-alone diagnostic. Optical diagnostic devices for melanoma detection and electrical impedance spectrometers are both examples of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma. FDA believes that computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma can facilitate more accurate triaging and management of those lesions. The devices can provide physicians trained in the clinical diagnosis and management of skin cancer an additional source of adjunctive information when triaging patient care for melanoma.

IV. Proposed Reclassification and Summary of Reasons for Reclassification

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify optical diagnostic devices for melanoma detection and electrical impedance spectrometers from class III into class II, subject to premarket notification (510(k)) requirements. FDA believes that there is sufficient information to establish special controls, and that these special controls, together with general controls, are necessary to provide a reasonable assurance of the safety and effectiveness of optical diagnostic devices for melanoma detection and electrical impedance spectrometers, to be renamed computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma. Optical diagnostic devices for melanoma detection and electrical impedance spectrometers are prescription devices, and under this proposed order, if finalized, computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma will be prescription devices. As such, the devices must satisfy prescription labeling requirements (see § 801.109 (21 CFR 801.109), *Prescription devices*). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of § 801.109 are met.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma, FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of these devices. Therefore, the Agency does not intend to exempt these proposed class II devices from 510(k) requirements. If this proposed order is finalized, persons who intend to market a computer-aided device which provides adjunctive diagnostic information about lesions suspicious for melanoma will need to submit to FDA a 510(k) and receive clearance prior to marketing the device.

FDA believes that there is sufficient information available to FDA through the MELAFIND PMA and associated Panel considerations of that PMA,[2] published peer-reviewed literature, and FDA's publicly available MDR database, Manufacturer and User Facility Device Experience (MAUDE) database, and Medical Device Recall database to establish special controls that effectively mitigate the risks to health identified in section V. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

V. Public Health Benefits and Risks to Health

FDA is providing a substantive summary of the valid scientific evidence concerning the public health benefits of the use of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma, and the nature (and if known, the incidence) of the risks of the devices (see further discussion of the special controls being proposed to mitigate these risks in section VII of this proposed order). FDA reviewed data in the PMA for MELAFIND (P090012) available to FDA under section 520(h)(4) of the FD&C Act, input from the 2010 Panel on P090012, published peer-reviewed literature, and postmarket information regarding computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma.

Computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma provide a benefit to the public health by facilitating more accurate triaging and management of those lesions. The devices can provide physicians trained in the clinical diagnosis and management of skin cancer an additional source of adjunctive information when triaging patient care for melanoma.

FDA has identified the following risks to health associated with the use of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma:

- *False negative or false positive results*—False negative results could result in complications such as incorrect or delayed diagnoses and delays in biopsy decisions and melanoma treatment, which may allow an undetected condition to worsen and potentially increase morbidity and mortality. False positive results may result in complications such as incorrect management of the patient, including unnecessary additional invasive biopsy procedures and more frequent screenings, as well as the potential administration of inappropriate treatments and/or the withholding of appropriate treatments, with possible adverse effects.
- *Use error/improper device use*—The device could be misused to analyze images from an unintended patient population, an unintended anatomical site, or lesions having an unintended attribute, or to analyze images acquired with incompatible imaging hardware or incompatible image acquisition parameters, potentially resulting in the device not operating at its expected performance level. The device could also be misused if the user does not follow the appropriate reading protocol for using the device to assess lesions of interest, which may lead to lower accuracy. Inaccurate results may result in the same complications associated

[2] In accordance with section 520(h)(4) of the FD&C Act, FDA has not relied on information in PMAs and PMA supplements approved within the last 6 years to develop proposed special controls or to otherwise inform the proposed reclassification.

with false negative or false positive results as discussed above.

- *Device failure/malfunction*—Device failure or malfunction could result in the absence or delay of device output, or incorrect device output, which could lead to inaccurate patient assessment. Inaccurate results may result in the same complications associated with false negative or false positive results as discussed above.
- *Electrical, thermal, mechanical, or light-related injury*—While in operation, the device may discharge electricity that could shock the user or patient. Electrical discharge or exposure to device-generated heat may cause thermal injury or discomfort. Moving parts may cause mechanical injury. For devices that utilize energy (*e.g.,* light) to provide adjunctive diagnostic information, accidental eye exposure to the energy source could cause eye injury.
- *Interference with other devices*—Individuals with electrically powered implants could experience an adverse interaction with the device due to electromagnetic interference or radiofrequency interference.
- *Adverse tissue reaction*—A patient could experience skin irritation and/or allergic reaction associated with the use and operation of the device via the use of non-biocompatible materials in patient-contacting devices.
- *Infection/cross contamination*—If components of the device that must be sterile are not adequately sterilized or if reusable components are not adequately reprocessed between uses, the device may introduce pathogenic organisms to patients and cause an infection.

VI. Summary of Data Upon Which the Reclassification Is Based

FDA has considered and analyzed the following information: (1) data in PMA P090012, (2) input from the 2010 Panel on P090012, (3) published peer-reviewed literature, and (4) FDA's publicly available MDR, MAUDE, and Medical Device Recall databases. The available evidence demonstrates that there are public health benefits derived from the use of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma. In addition, the nature of the associated risks to health are known, and special controls can be established to sufficiently mitigate these risks.

FDA is proposing a single generic device type for computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma. Although the different modalities included in this proposed order have different technological characteristics in certain respects (*e.g.,* the use of visible and infrared optical radiation vs. the use of an electrode to measure electrical impedance), FDA believes that these devices have sufficiently similar purposes, designs, functions, and other features related to safety and effectiveness such that the same regulatory controls are necessary and sufficient to provide reasonable assurance of safety and effectiveness. FDA believes that a single generic device type is therefore appropriate for these devices.

On June 9, 2009, FDA filed a PMA (P090012) from MELA Sciences, Inc. for the MELAFIND, an optical diagnostic device for melanoma detection. This device is to be used by physicians trained in the clinical diagnosis and management of skin cancer (*i.e.,* dermatologists) and further trained in the appropriate use of the device, for use on clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma. It is intended to provide adjunctive information to a dermatologist considering biopsy of a suspicious lesion and is not intended to be used to confirm a clinical diagnosis of melanoma. Data provided in the PMA supported that there is a reasonable assurance of safety and effectiveness of this device when used as indicated above. These data included the results of a pivotal clinical trial of MELAFIND, which met its primary safety and effectiveness endpoints by achieving at least 95 percent sensitivity at a 95 percent confidence level to malignant melanoma among lesions with dermatological diagnoses of ''Melanoma cannot be ruled out'' or ''Not melanoma'' (the sensitivity achieved in the study was 98.3 percent), and by achieving a superior pooled specificity (10.6 percent) compared to the study dermatologists (5.5 percent) for lesions that were not malignant, among lesions with dermatological diagnoses of ''Melanoma cannot be ruled out'' or ''Not melanoma.'' Additionally, no direct adverse events (AEs) [3] were reported for the patients enrolled in the MELAFIND pivotal study.

At an advisory committee meeting held on November 18, 2010, the Panel discussed the MELAFIND PMA. The Panel raised concerns regarding, among other things, the use of the MELAFIND device by non-dermatologists, and regarding the use of the device by untrained operators. The Panel, as well as the PMA, also identified false negatives as a potential risk that could result in delayed care, which would be a significant safety concern if unmitigated. When FDA subsequently approved the device, the approval was limited to use as an adjunct to physician decision making and by physicians trained in the clinical diagnosis and management of skin cancer (*i.e.,* dermatologists) who have also successfully completed a training program for the device. Notably, lesions that were clinically suspicious for melanoma would not be evaluated by MELAFIND, and a MELAFIND negative reading would be only part of the assessment for a clinical decision to biopsy, and would not replace clinical judgement (Ref. 1).

FDA also performed a literature search to evaluate data related to optical diagnostic devices for melanoma detection and electrical impedance spectrometers. Published data were found in the literature relevant to optical diagnostic devices for melanoma detection and electrical impedance spectrometers.

The clinical performance of an electrical impedance spectrometer was assessed in a multicenter, prospective, blinded clinical trial published in 2014 (Ref. 9). This study focused on the safety and effectiveness of the device for distinguishing benign skin lesions from melanoma. Eligible skin lesions in the study were examined with the device, photographed, excised, and subjected to histopathological evaluation. One thousand, nine hundred and fifty one patients with 2416 lesions were enrolled; 1943 lesions were eligible and evaluable for the primary efficacy end point,[4] including 265 melanomas. The sensitivity of the device was measured to be 96.6 percent with a specificity of 34.4 percent, meeting the pre-specified study co-primary endpoints of sensitivity ≥0.90 to detect malignant melanoma and non-randomness (odds ratio greater than 1) to aid physicians in melanoma assessment. A total of 36 AEs were observed in 28 patients (1.5 percent), out of which only 3 AEs (occurring on three patients (0.2 percent)) were defined as definitely related to the device. No serious AEs, serious adverse device effects, or unanticipated adverse device effects were observed. The study concluded that the electrical impedance

[3] In this trial, direct adverse events included device-related adverse events, and did not include false negative results that may lead to delays in the timely diagnosis of melanoma cancer and treatment.

[4] The study had two co-primary analyses: a one-sided exact 95 percent confidence bound of the sensitivity in detecting cutaneous melanoma of >90 percent%; and nonrandom result at the given sensitivity, *i.e.,* sensitivity + specificity >1.0.

spectrometer was accurate and safe as a support tool for the detection of cutaneous melanoma by physicians trained in the clinical diagnosis of skin cancer.

In addition, literature reviews of melanoma detection technologies conclude that optical diagnostic devices for melanoma detection and electrical impedance spectrometers are effective as adjunctive sources of information for physicians trained in the clinical diagnosis and management of skin cancer considering biopsy of lesions suspicious for melanoma when they have high sensitivity (*e.g.,* over 90 percent) (Refs. 10–13). These reviews acknowledge that the specificity of these devices can be relatively low, but conclude that the low specificity and low positive predictive value is acceptable when there is very high sensitivity and negative predictive value associated with these devices. Data cited in these reviews support that these devices generally are more sensitive than visual inspection of suspicious lesions without magnification, and that when they are more sensitive than visual inspection, the benefits of using these devices to provide adjunctive information outweigh the risks related to false positives resulting in unnecessary biopsies because the adjunctive information provided by the device can facilitate detection of melanoma that may otherwise go undetected. One review concludes that the use of these devices as part of the biopsy decision making process increases the overall sensitivity for malignant melanoma detection, which justifies the low specificity and high biopsy number due to improved detection of malignant melanoma (Ref. 10).

The totality of the literature reviewed indicates that false results and unnecessary biopsies are among the potential risks related to the use of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma (Refs. 1–2, 9–10). The literature reviewed support that these risks can be successfully mitigated by ensuring that the devices are highly sensitive, specifying that the devices are intended to be used to provide adjunctive information for clinical decision making rather than for giving a conclusive diagnosis, and ensuring that the user population are physicians trained in the clinical diagnosis and management of skin cancer and that labeling includes information on the appropriate training for these physicians to use the device (Refs. 11–13).

Finally, a search of FDA's publicly available MDR database revealed no medical device reports for product codes OYD and ONV, the product codes included in this reclassification. A search of FDA's publicly available recall database revealed no entries for devices under the ONV product code and a single entry for a device approved under the OYD product code, posted on May 20, 2015. This Class II recall was conducted due to a software change for the device's user interface that lacked the requisite FDA approval. This recall affected approximately 65 units of the device and was terminated on May 4, 2016. A search of FDA's publicly available MAUDE database revealed no entries for devices under the OYD product code and a single entry for a device approved under the ONV product code. A review of the single entry in the MAUDE database for the ONV product code revealed that the product code was misidentified in the report, as evidenced by the fact that the event date for the entry was May 14, 2014, which was before FDA had approved any devices under this product code.

Based on our review of the information described above, FDA has determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma, and that sufficient information exists to establish such special controls. Therefore, FDA, on its own initiative, is proposing to reclassify these devices from class III into class II (special controls), and subject to premarket notification (510(k)) requirements.

VII. Proposed Special Controls

FDA believes that the following proposed special controls would mitigate each of the risks to health described in section V and that these special controls, in addition to general controls, would provide a reasonable assurance of safety and effectiveness for computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma.

The risk of false positive results and false negative results can be mitigated through clinical performance testing, which may include, for example, stand-alone test(s) with acceptable performance thresholds (*e.g.,* sensitivity and specificity), side-by-side comparison(s), and/or a reader study, as applicable, as well as non-clinical performance testing. The clinical performance testing must demonstrate that the device improves assisted-read detection and/or diagnostic characterization of lesions suspicious for melanoma compared to characterization of lesions without the device in the indicated user population(s) when used in accordance with the instructions for use. The non-clinical performance testing, among other things, must demonstrate that the device performs as intended under anticipated conditions of use. The risk of false positive results and false negative results can be further mitigated by special controls that require information in labeling to provide detailed instructions for use and inform the user of the expected device performance on a dataset representative of the intended population.

The risk associated with use error and inappropriate use of a computer-aided device which provide adjunctive diagnostic information about lesions suspicious for melanoma can be mitigated by requiring that the following information be included in the device labeling: (1) the intended patient population (*e.g.,* gender, Fitzpatrick Skin Type); (2) anatomical site(s); (3) type(s) of lesions; (4) compatible imaging hardware; and (5) compatible image acquisition parameters needed for the device to achieve its intended use. This risk can be further mitigated by special controls that require the device labeling to inform intended users of foreseeable situations in which the device is likely to fail or not to operate at its expected performance level. The risk resulting from not following the intended reading protocol can be mitigated by requiring that the device labeling include a device description and information needed to facilitate the clinical interpretation of all device outputs, and by special controls requiring that the device labeling provide a description of user training required prior to use. This risk can be further mitigated by special controls that require a human factors assessment to demonstrate that intended users can correctly use the device according to the intended use following user training.

The risk of device failure or malfunction can be mitigated by requiring non-clinical performance testing and software verification, validation, and hazard analysis, and by requiring that information needed to facilitate the clinical interpretation of all device outputs be included in the labeling (*e.g.,* negative/positive result, risk score). This risk can be further mitigated by special controls that require the device labeling to inform intended users of foreseeable situations in which the device is likely to fail or

not to operate at its expected performance level.

The risk of electrical, thermal, mechanical, and light-related hazards leading to user injury or discomfort can be mitigated by special controls that require testing that demonstrates: (1) electrical, mechanical, and thermal safety; (2) software verification, validation and hazard analysis; and (3) device labeling that includes instructions on appropriate usage and maintenance of the device. The risk of eye injury due to energy (*e.g.,* light) exposure can be mitigated by special controls that require labeling that warns users about exclusion of lesions close to the eye and unsafe energy exposure to the eyes.

The risk that the device may interfere with other devices due to radiofrequency or electromagnetic interference can be mitigated by requiring testing that demonstrates electromagnetic compatibility.

The risk of adverse tissue reaction for patient-contacting devices can be mitigated by special controls that require elements of the device that may contact the patient to be demonstrated to be biocompatible and labeling that includes, in addition to user qualifications needed for safe use of the device, instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

The risks of infection and cross contamination for patient-contacting components can be mitigated by special controls that require sterilization validation, shelf-life testing, and labeling that includes validated methods and instructions for reprocessing of any reusable components.

Table 1 shows how FDA believes each risk to health described in section V would be mitigated by the proposed special controls.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR COMPUTER-AIDED DEVICES WHICH PROVIDE ADJUNCTIVE DIAGNOSTIC INFORMATION ABOUT LESIONS SUSPICIOUS FOR MELANOMA

Identified risk to health	Mitigation measures
False negative or false positive results	Clinical performance testing, non-clinical performance testing, labeling.
Use error/improper device use	Human factors assessment; labeling, including a description of user training.
Device failure/malfunction	Non-clinical performance testing, labeling, software verification, validation, and hazard analysis.
Electrical, thermal, mechanical, or light-related injury.	Electrical, mechanical, and thermal safety testing, labeling, software verification, validation, and hazard analysis.
Interference with other devices	Electromagnetic compatibility testing.
Adverse tissue reaction	Biocompatibility evaluation, labeling.
Infection and cross contamination	Sterilization validation, shelf-life testing, labeling.

If this proposed order is finalized, optical diagnostic devices for melanoma detection and electrical impedance spectrometers will be reclassified into class II (special controls) as computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma and will be subject to premarket notification requirements under section 510(k) of the FD&C Act. Firms submitting a 510(k) for such a device will be required to comply with the particular mitigation measures set forth in the special controls. FDA believes that adherence to the special controls, in addition to the general controls, is necessary to provide a reasonable assurance of safety and effectiveness of computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. This proposed order refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

X. Proposed Effective Date

FDA proposes that any final order based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

XI. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3) of the FD&C Act, in the proposed order, we are proposing to codify computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma in the new 21 CFR 878.1820, under which computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma would be reclassified into class II.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. P090012 Summary of Safety and Effectiveness Data, available at: *https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090012B.pdf.*

2. A. Hauschild, *et al.* ''To Excise or Not: Impact of MELAFIND on German Dermatologists' Decisions to Biopsy

Atypical Lesions.'' *Journal der Deutschen Dermatologischen Gesellschaft.* 12(7):606–614. June 2014.
3. R.R. Winkelmann, *et al.* ''Enhancement of International Dermatologists' Pigmented Skin Lesion Biopsy Decisions Following Dermoscopy with Subsequent Integration of Multispectral Digital Skin Lesion Analysis.'' *Journal of Clinical and Aesthetic Dermatology.* 9(7):53–5. July 2016.
4. R. Wells, *et al.* ''Comparison of Diagnostic and Management Sensitivity to Melanoma Between Dermatologists and MELAFIND: A Pilot Study.'' *Archives of Dermatology.* 148(9):1083–4. September 2012.
5. L.F. di Ruffano, *et al.* ''Computer-Assisted Diagnosis Techniques (Dermoscopy and Spectroscopy-Based) for Diagnosing Skin Cancer in Adults.'' Cochrane Skin Cancer Diagnostic Test Accuracy Group; *Cochrane Database System Review.* 4;12(12). December 2018.
* 6. FDA, November 18, 2010, Meeting of the General and Plastic Surgery Devices Panel Meeting Materials (available at *https://wayback.archive-it.org/7993/20170403223449/https:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/ucm205684.htm*).
* 7. FDA, November 18, 2010, Meeting of the General and Plastic Surgery Devices Panel, 24-Hour Summary (available at *https://wayback.archive-it.org/7993/20170403223449/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM234481.pdf*).
* 8. P090012 Approval Order, available at *https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090012A.pdf.*
9. J. Malvehy, *et al.* ''Clinical Performance of the NEVISENSE System in Cutaneous Melanoma Detection: An International, Multicentre, Prospective and Blinded Clinical Trial on Efficacy and Safety.'' *British Journal of Dermatology.* 171(5):1099–1107. May 2014.
10. R.P. Braun, *et al.* ''Electrical Impedance Spectroscopy in Skin Cancer Diagnosis.'' *Dermatologic Clinics.* 35(4):489–493. October 2017.
11. D.N. Dorrell and L.C. Strowd. ''Skin Cancer Detection Technology.'' *Dermatologic Clinics.* 37(4):527–536. October 2019.
12. C. Fink and H.A. Haenssle. ''Non-Invasive Tools for the Diagnosis of Cutaneous Melanoma.'' *Skin Research and Technology,* pp. 261–271, 23 (3) (2017).
13. R.R. Winkelmann, A.S. Farberg, A.M. Glazer, *et al.* ''Noninvasive Technologies for the Diagnosis of Cutaneous Melanoma.'' *Dermatologic Clinics,* pp. 453–456, 35 (4) (2017).

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.1820 to subpart B to read as follows:

§ 878.1820 Computer-aided devices which provide adjunctive diagnostic information about lesions suspicious for melanoma.

(a) *Identification.* A computer-aided device which provides adjunctive diagnostic information about lesions suspicious for melanoma is a device that is used to aid in the decision-making process for melanoma detection. The device is intended for prescription use by a physician trained in the clinical diagnosis and management of skin cancer (*e.g.,* a dermatologist) on skin lesions with one or more clinical or historical characteristics of melanoma, and is based on a computer algorithm to analyze optical or other physical properties of a skin lesion. The algorithm returns a classification of the skin lesion regarding melanoma when a physician trained in the clinical diagnosis and management of skin cancer chooses to obtain additional information when considering biopsy. The device is not for use as a stand-alone diagnostic.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device improves assisted-read detection or diagnostic characterization of lesions suspicious for melanoma compared to characterization of lesions without the device in the indicated user population(s) when used in accordance with the instructions for use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Such testing must include testing of safety features intended to mitigate device specific hazards and must demonstrate:

(i) Electromagnetic compatibility, and electrical, mechanical, and thermal safety.

(ii) Continued sterility and package integrity of components that must be sterile, as well as continued device functionality, over the identified shelf life of the device.

(3) Sterilization validation must be conducted for components that must be sterile.

(4) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

(6) A human factors assessment must demonstrate that the intended user can correctly use the device according to the intended use following user training.

(7) Labeling must include:

(i) A description of the device and information needed to facilitate clinical interpretation of all device outputs.

(ii) Information regarding the intended patient population and anatomical site(s), type(s) of lesions, compatible hardware, and compatible image acquisition parameters used with the device in order to achieve the intended use.

(iii) A summary of any clinical testing conducted to demonstrate how the device functions in providing information about the skin lesion. The summary must include the following:

(A) A description of each device output and clinical interpretation.

(B) Any performance measures, including sensitivity and specificity.

(C) Relevant characteristics of the patients studied in the clinical validation (including age, gender, race or ethnicity, disease category), inclusion and exclusion criteria, and a summary of validation results.

(D) The expected performance of the device for all intended use populations.

(iv) A statement that the device is not intended for use as a stand-alone diagnostic.

(v) User qualifications needed for safe use of the device, including a description of user training required prior to use, and a statement that the device is intended to be used by a physician trained in the clinical diagnosis and management of skin cancer (*e.g.,* a dermatologist).

(vi) Warnings and cautions to mitigate any device specific hazards, including the following:

(A) Identifying foreseeable situations in which the device is likely to fail or not to operate at its expected performance level; and

(B) For devices that utilize energy to provide adjunctive diagnostic information, unless available information demonstrates that the specific warnings and cautions do not apply, a statement warning users about exclusion of lesions close to the eye and unsafe energy exposure to the eyes.

(vii) Instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13954 Filed 6–29–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket No. OSHA–2022–0008]

RIN 1218–AD41

Massachusetts State Plan for State and Local Government Employers; Notification of Submission; Proposal To Grant Initial State Plan Approval; Request for Public Comment and Opportunity To Request Public Hearing

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; request for written comments; notification of opportunity to request informal public hearing.

SUMMARY: The Massachusetts Department of Labor Standards (the DLS) has submitted a developmental State Plan for occupational safety and health, applicable only to State and local Government employment (workers of the State and its political subdivisions) (Massachusetts State Plan), for determination of initial approval under Section 18 of the Occupational Safety and Health Act of 1970 (the OSH Act). In this notification, OSHA proposes to grant the Massachusetts State Plan initial approval based on its preliminary assessment that the Massachusetts State Plan meets, or will meet within three years, OSHA's State Plan approval criteria, and that Massachusetts has provided adequate assurances that it will be at least as effective as Federal OSHA in protecting the safety and health of Massachusetts state and local government workers. OSHA proposes to fund initial approval of the Massachusetts State Plan from the State Plan funding available in the Department of Labor's Fiscal Year 2022 budget.

DATES:

Written Comments: Comments and requests for a hearing must be submitted by August 1, 2022.

Informal public hearing: Any interested person may request an informal hearing concerning the initial approval of the State Plan. OSHA will hold such a hearing if the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) finds that substantial objections have been filed. After the close of the comment period, the Assistant Secretary will review all comments submitted; will review all hearing requests; and will schedule an informal hearing if a hearing is required to resolve substantial issues.

Publication in Massachusetts: No later than 5 days following the date of publication of this notification in the **Federal Register**, Massachusetts shall publish, or cause to be published, reasonable notice within the State containing the same information contained herein.

ADDRESSES: *Written comments:* You may submit written comments and requests for an informal hearing electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the online instructions for making electronic submissions.

Instructions. All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2021–0008).[1] All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want made available to the public or submitting materials that contain personal information (either about themselves or others), such as Social Security Numbers and birthdates. Submissions must clearly identify the issues addressed and the positions taken.

Docket: To read or download comments or other material in the docket, go to Docket No. OSHA–2022–0008 at *www.regulations.gov.* All comments and submissions are listed in the *www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that website. All comments and submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877)889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Contact Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general and technical information: Contact Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, U.S. Department of Labor; telephone: (202) 693–2200; email: *kalinowski.doug@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 18 of the OSH Act, 29 U.S.C. 667, provides that a State which desires to assume responsibility for the development and enforcement of standards relating to any occupational safety and health issue with respect to a Federal standard which has been promulgated may submit a State Plan to the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) documenting the proposed program in detail. State and local government employers are excluded from Federal OSHA coverage under the Act (29 U.S.C. 652(5)). However, a State may submit a State Plan for the development and enforcement of occupational safety and health standards applicable only to employees of the State and its political subdivisions (State and local Government employees) (29 CFR 1956.1). The Assistant Secretary will approve a State Plan for State and local Government employees if the Plan provides for the development and enforcement of standards relating to hazards in employment covered by the Plan which are or will be at least as effective in providing safe and healthful employment and places of employment as standards promulgated and enforced under Section 6 of the Act, giving due consideration to differences between State and local Government and private sector employment (29 U.S.C. 667(c); 29 CFR 1956.2(a)). In making this determination, the Assistant Secretary will measure the State Plan against the criteria and indices of effectiveness set forth in 29 CFR part 1956.10 and 1956.11 (29 CFR 1956.2(a)). A State Plan for an occupational safety and health program for State and local Government employees may be approved although it does not yet fully meet this criteria, if it includes satisfactory assurances by the State that it will take the necessary steps to bring the program into conformity with these criteria within the 3-year period immediately following the commencement of the State Plan's operation (29 CFR 1956.2(b)(1)). In such

[1] Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number plus a unique four-digit code.