IOWA DEPARTMENT OF PUBLIC HEALTH
Bureau of Radiological Health (BRH)
Lucas State Office Building, 5th Floor
321 East 12th Street, Des Moines, IA 50319
November, 2014

IDPH INFORMATION NOTICE: 2014 T-01: New requirements for tanning unit labeling

ADDRESSEES: All tanning facility owners

PURPOSE

IDPH is issuing this notice to inform all tanning facility owners of new FDA requirements for the labeling on tanning units. This is informational only. Further notices will be issued when the current 641 Iowa Administrative Code (136D) 46 rules for tanning are revised.

REFERENCES

FDA Code of Federal Regulations
21 CFR part 878.4635 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.
(b)(6) Labeling-(i) Sunlamp products.
(A) The warning statement below must appear on all sunlamp products and must be placed in a black box. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (for tanning booth door) is open or closed when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height). Labeling on the device must include the following statement:

Attention: This sunlamp product should not be used on persons under the age of 18 years.

DISCUSSION

The FDA has changed the requirements for the labeling on all tanning units according to the above reference. This is part of the FDA's move in reclassifying tanning units from Class I (general controls) exempt from premarket notification to Class II (special controls) subject to premarket notification. What this means is that all tanning unit manufacturers must submit a marketing plan to FDA that shows compliance with 21 CFR Part 878.4635 above. This also covers all units previously sold.

Therefore, manufacturers must add the new labeling to all new units sold and provide the new labeling for all units previously sold. The manufacturers are to supply the additional labeling for all units by August 26, 2015.

WHAT THIS MEANS FOR YOUR UNITS

1. You may be contacted by your tanning unit supplier or manufacturer about the new labeling.
2. You may wish to contact your tanning unit supplier and request the labeling, or contact the manufacturer if you purchased the unit directly from them.
3. If the manufacturer is no longer in business, you will be required to make and affix the required labeling. We will send more guidance about this as it is developed.
4. THIS DOES NOT MEAN THAT PERSONS UNDER THE AGE OF 18 YEARS ARE RESTRICTED FROM TANNING. This is a labeling requirement only.

CONCLUSION

Additional labeling will be required for each tanning unit. The labeling does not mean that you must prohibit persons under the age of 18 years from tanning. IDPH will be revising 641 IAC (136D) 46 rules to include the new labeling requirements, and will send additional information as it is available.

If you have any questions regarding this Notice, please contact the Bureau of Radiological Health at 515-281-0430 or by email at adperehreg@idph.iowa.gov .

_____ _____

Angela Leek, MS
Chief, Bureau of Radiological Health

Date