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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

re: request for variances for DEFLEXION, a new, non-medical product which incorporates class II laser diodes

To whom it may concern:

We request variances to the requirements specified in paragraphs (f)(5) and (f)(6) of Title 21, Chapter I, Subchapter J, PART 1040, Sec. 1040.10, "Laser products". These requirements are specified as:

(f)(5) Laser radiation emission indicator. (i) Each laser system classified as a Class II or IIIa laser product shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

(f)(6) Beam attenuator. (i) Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and table VI.

Our request for variances is based upon the two requirements being inappropriate for our particular product, DEFLEXION. DEFLEXION is a two player, strategy board game which is played on a hard plastic, injection molded game board which has two built-in, class II laser diodes. Players take turns moving pieces which contain plastic mirrored surfaces. After moving a piece, a player concludes his or her turn by depressing a red button to momentarily energize one of the diodes. The goal is to position the mirrored pieces such that the laser light will reflect in the direction of the opponent's key piece and end the game. The pieces fit into square sockets molded into the board's surface, and the mirrors on those pieces are oriented to be perpendicular to the board surface. This causes

2005U-0181 UAR1

the beams to always travel in paths which are parallel to the board, at a constant height of about 12 mm (0.5 in). The board is molded such that part of it forms a raised frame all around the periphery, 25mm (1in) high. Thus, anytime the laser light doesn't terminate at a non-mirrored surface of one of the playing pieces, the frame prevents the light from escaping from the confines of the board.

We have prepared an initial Laser Product Report, please find it attached.

Justification for variance to emission indicator
The laser diodes are energized by depressing an adjacent, intermittent switch; the lasers will not emit light without the willful act of the operator holding down a red button. The operator will always be aware of emission. Furthermore, the 635nm wavelength red light is in the visible spectrum and is evident whenever present.

Justification for variance to beam attenuator
Since class II diodes are used, with a maximum output below 1mW, the primary concern for collateral radiation is for eye exposure. While the game board does permit hands which are placed near the game board surface to be impinged upon by a beam, care was taken in designing and incorporating the frame around the periphery of the game board which keeps the beams confined within the area above the board surface. The diodes were placed in corners near the junction of two sides of the bounding frame to preclude eyes from accidentally being positioned in the beams' paths.

Please contact me if you have any questions or concerns regarding the request for variance.

Regards,

Del Segura

Del Segura
Deflexion, LLC