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November 13, 2013

New Hampshire Board of Chiropractic Examiners
Department of Health and Human Services
129 Pleasant Street
Concord, NH 03301

Re: Dry Needling and Violations of the U.S. Food, Drug, and Cosmetic Act (FDCA) and Food and Drug Administration Rules

Dear State Board of Chiropractic:

I write on behalf of the National Center for Acupuncture Safety and Integrity (NCASI), a nonprofit corporation working to protect the public from the unlicensed practice of acupuncture and the illegal sale and use of acupuncture needles. NCASI is aware that a number of state boards of physical therapy have authorized physical therapists to practice what is referred to as "trigger-point dry needling" ("TPDN"), also known as "dry needling." Those promoting "TPDN" openly acknowledge that they are using labeled acupuncture needles to practice "TPDN," but claim that "TPDN" falls outside the statutory and regulatory definitions of practicing acupuncture. While specific state laws vary on the definition of the practice of acupuncture, the federal Food and Drug Administration ("FDA") strictly regulates the sale of acupuncture needles as Class II prescription medical devices under the U.S. Food, Drug, and Cosmetic Act (FDCA) only to qualified and licensed acupuncture practitioners. Specifically, FDA regulations restrict that the sale of acupuncture needles to anyone but a person *authorized to practice acupuncture* and *for use in acupuncture*. The sale of acupuncture needles to anyone other than a qualified and licensed acupuncture practitioner is a violation of both the FDCA and the FDA rules described below.

Please be aware that to the extent your board authorizes the use of acupuncture needles by persons who are not explicitly authorized to practice *acupuncture*, your actions are inconsistent with federal law and could expose your state board to liability in the event a person is injured by one of the practitioners your board regulates. There is no dispute that the practice of "TPDN" absolutely depends on the use of FDA-regulated acupuncture needles. Any official sanctioning of "TPDN" by a state professional board signals to potential patients that those practicing "TPDN" are qualified, trained and legally authorized to possess, purchase and use acupuncture needles, a Class II prescription medical device under FDA regulations. As a result,

state regulatory and professional boards that endorse the practice of "TPDN" by persons who are not explicitly authorized to practice acupuncture is inconsistent with federal law.

FDA's regulation of acupuncture needles as Class II prescription medical devices

Acupuncture needles are regulated under the FDCA as Class II prescription medical devices that are subject to FDA's strict prescription sale requirements. *See* 21 CFR § 880.5580 (Exhibit A); 61 Fed. Reg. 64616–64617 (Dec. 6, 1996) (Exhibit B); Reclassification Order Docket No: 94P-0443 Acupuncture Needles for the Practice of Acupuncture (Mar. 29, 1996) (Exhibit C); 21 CFR § 801.109 (Exhibit D). In authorizing the sale of acupuncture needles, the FDA was explicit that such needles "must be clearly restricted to *qualified practitioners of acupuncture* as determined by the States." 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added).

In reclassifying acupuncture needles from Class III to Class II prescription medical devices, the FDA also plainly defined acupuncture needles stating: "[a]n acupuncture needle is a device intended to pierce the skin *in the practice of acupuncture. ...*" 21 CFR § 880.5580(a) (emphasis added). The sale and introduction of acupuncture needles into interstate commerce for any purpose other than for "the practice of acupuncture" is outside the scope of FDA's approval and would make such needles legally "adulterated" and/or "misbranded" under the FDCA. 21 U.S.C. § 352(f)(1); 21 U.S.C. § 331(p); 21 U.S.C. § 352(o).

Consistent with this directive, the FDA requires that acupuncture needles, including those that are being used for "TPDN," carry a prescription label stating: "Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States." 21 CFR 801.109(b)(1); 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added); *See also* Exhibit E. NCASI is committed to seeing enforcement of this common sense public safety requirement.

Sale of acupuncture needles to those who are not qualified to practice acupuncture

NCASI is aware that many individual physical therapists, occupational therapists, naturopaths, chiropractors, athletic trainers and others are attempting to skirt state acupuncture licensing laws by claiming they are using acupuncture needles to practice "TPDN" as opposed to "acupuncture." Some state regulatory boards have authorized "TPDN" by regulation absent any apparent awareness or consideration of FDA's regulation of acupuncture needles as Class II prescription medical devices.

The FDA, however, has explicitly limited the sale of acupuncture needles to those *authorized to practice acupuncture* and has only approved the use of such needles *for the purpose of acupuncture*. It is therefore illegal for an individual to sell, purchase, receive or use an acupuncture needle unless it is intended to be used for the practice of acupuncture by a person who is authorized under state law to practice acupuncture.

The purchase and receipt of acupuncture needles by individuals who are not qualified to practice acupuncture or for intended uses other than acupuncture make such needles legally "adulterated" and/or "misbranded" under the FDCA and is in direct violation of the FDCA and

FDA's implementing regulations. 21 U.S.C. §§ 331(a)–(c), (p); 21 U.S.C. § 352(o); 21 U.S.C. § 352(f)(1); 21 U.S.C. § 351(f); 21 CFR § 801.109(a). While a number of companies are illegally selling acupuncture needles on-line to persons who are not authorized to practice acupuncture, this does not legalize the practice. NCASI is currently investigating these sales and has submitted targeted complaints to the FDA.

With this letter your board and your state have notice that to the extent your board approves or otherwise endorses the use of acupuncture needles for the practice of "TPDN" by persons who are not legally authorized to practice acupuncture you may be exposing your board to liability for endorsing a practice that involves the violation of FDA regulations and the unauthorized use of a Class II medical device.

NCASI encourages your board to carefully review the enclosed regulations and other documents related to the regulation of acupuncture needles. To the extent your board has already endorsed or approved the practice of "TPDN" by persons who are not authorized to practice acupuncture, NCASI encourages your board to reconsider such actions. If your board has yet to address the issue of "TPDN," we encourage you to take a position that is consistent with the FDA's regulation of acupuncture needles as Class II prescription medical devices.

Thank you for your careful consideration of these issues.

Very truly yours,

R. Scott Jerger
Jonathan C. Smale

cc: client
Enclosures

Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2013]
[CITE: 21CFR880.5580]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart F--General Hospital and Personal Use Therapeutic Devices

Sec. 880.5580 Acupuncture needle.

(a)*Identification*. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b)*Classification*. Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

Exhibit A

Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

This regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: December 2, 1996.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)).

2. Appendix 1 to subpart P of part 404 is amended by revising item 1 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

1. Growth Impairment (100.00): December 7, 1998.

* * * * *

[FR Doc. 96–31037 Filed 12–5–96; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket Number 94P–0443]

Medical Devices; Reclassification of Acupuncture Needles for the Practice of Acupuncture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III (premarket approval) into class II (special controls). FDA is also announcing it has issued an order in the form of a letter to the Acupuncture Coalition reclassifiying acupuncture needles. This action is in response to petitions filed by the Acupuncture Coalition and in keeping with, but not dependent upon, the recommendation of FDA's Anesthesiology Devices Advisory Panel (the Panel). This action is being taken because the agency believes that there is sufficient information to establish that special controls will provide reasonable assurance of the safety and effectiveness of acupuncture needles.

EFFECTIVE DATE: December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION: On December 6, 1995, FDA filed reclassification petitions from the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France; Seirin-Kasei (Mfg.), Japan; Ito Co., Japan; and Ido-No-Nippon-Sha, Japan, requesting reclassification of acupuncture needles from class III to class II. On March 29, 1996, FDA issued an order (Ref. 1) in the form of a letter, to the petitioners reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III to class II. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and § 860.134 (21 CFR 860.134) provide for the reclassification by order of devices not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments.

Under section 513(f)(2) of the act and § 860.134, FDA may refer a reclassification petition to an appropriate panel. Although FDA did not refer the reclassification petitions submitted by the Acupuncture Coalition to a panel, the Anesthesiology Devices Advisory Panel (the Panel) had previously considered the classification of acupuncture needles and other acupuncture devices and recommended that acupuncture needles be placed into class II, as reported in the Federal Register of November 2, 1979 (44 FR 63292 at 63299) (Ref. 2). The supplemental data sheet completed by the Panel on November 30, 1976 (Ref. 3), listed sepsis, excessive trauma, and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use. FDA's decision to reclassify acupuncture needles as class II is in keeping with, but not dependent upon, the recommendation of the Panel.

FDA determined that acupuncture needles could safely be reclassified from class III to class II with the implementation of special controls. Acupuncture needles are devices intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle and may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

The order identified the special controls needed to provide reasonable assurance of the safety and effectiveness of acupuncture needles. Those special controls are in compliance with: (1) Labeling provisions for single use only and the prescription statement in § 801.109 (21 CFR 801.109) (restriction to use by or on the order of qualified practitioners as determined by the States), (2) device material biocompatibility, and (3) device sterility. FDA believes that information for use, including: Indications, effects, routes, methods, and frequency and duration of administration; and any hazards, contraindications, side effects, and precautions are commonly known to qualified practitioners of acupuncture. Therefore, under § 801.109(c), such indications do not need to be on the dispensing packaging, but sale must be clearly restricted to qualified practitioners of acupuncture as determined by the States. Guidance on the type of information needed to support biocompatibility and sterility of

Exhibit B

acupuncture needles is available in the General Hospital Branch guidance document entitled "Guidance on the Content of Premarket Notification (510(k)) Submissions for Hypodermic Single Lumen Needles" (draft), April 1993 (Ref. 4). A copy of this guidance document is available from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850–4307, 301–443–6597 or 800–638–2041 and FAX 301–443–8818.

Consistent with the act and the regulations, after thorough review of the clinical data submitted in the petitions, and after FDA's own literature search, on March 29, 1996, FDA sent the Acupuncture Coalition a letter (order) reclassifying acupuncture needles for general acupuncture use, and substantially equivalent devices of this generic type, from class III to class II (special controls). As required by § 860.134(b)(7), FDA is announcing the reclassification of the generic type of device. Additionally, FDA is amending part 880 (21 CFR part 880) to include the classification of acupuncture needles for the practice of acupuncture by adding new § 880.5580.

Environmental Impact

The agency has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Under 21 CFR 25.24(e)(2), the reclassification of a device is categorically exempt from environmental assessment and environmental impact statement requirements. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices from class III to class II will relieve some manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to the Acupuncture Coalition dated March 29, 1996.

2. Classification of anesthesiology devices, development of general provisions; 44 FR 63292 at 63299, November 2, 1979.

3. Anesthesiology Devices Advisory Panel's supplemental data sheet, November 30, 1976.

4. Guidance on the Content of Premarket (510(k)) Submissions for Hypodermic Single Lumen Needles (draft), April 1993.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 880.5580 is added to subpart F to read as follows:

§ 880.5580 Acupuncture needle.

(a) *Identification.* An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–31047 Filed 12–5–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR–4154–C–02]

RIN 2501–AC36

Revised Restrictions on Assistance to Noncitizens; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule, correction.

SUMMARY: On November 29, 1996 (61 FR 60535), HUD published an interim rule implementing the changes made to Section 214 of the Housing and Community Development Act of 1980 by the Use of Assisted Housing by Aliens Act of 1996. Section 214 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. The November 29, 1996 interim rule incorrectly provided for a public comment due date of November 29, 1996. The public comment due date should have been January 28, 1997, 60 days after publication of the November 29, 1996 interim rule. The purpose of this document is to correct the due date for public comments in the November 29, 1996 rule.

Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ref #1

MAR 29 1996

Acupuncture Coalition
C/O Mr. James S. Turner
and Mr. Frank M. Pascal
Swankin and Turner
1424 16th Street, N.W.
Suite 105
Washington, D.C. 20036

Re: Reclassification Order
Docket No. 94P-0443
Acupuncture Needles for the Practice of Acupuncture

Dear Mr. Turner and Mr. Pascal:

The Center for Devices and Radiological Health of the United States Food and Drug Administration (FDA) has completed its review of your petitions on behalf of the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France, Seirin-Kasei, Japan; Ito Co., Japan; Ido-No-Nippon-Sha, Japan and Seirin Kasei (Mfg.), for reclassification of acupuncture needles for the practice of acupuncture.

This order reclassifies acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type into class II, under the generic name: acupuncture needles.

FDA identifies acupuncture needles as devices intended to pierce the skin in the practice of acupuncture by qualified practitioners as determined by the States. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment. The device is intended for single use only.

As you know, on December 6, 1994, FDA filed your reclassification petitions requesting reclassification of acupuncture needles from class III to class II. The petitions were submitted under section 513(f)(2) of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. 360c(f)(2), and 21 CFR 860.134 of the agency's regulations. Acupuncture needles were automatically classified into class III under section 513(f)(1) of the act in accordance with a Federal Register Notice of May 9, 1973 (38 FR 6419): Acupuncture Devices Labeling . That notice stated that until scientific evidence is obtained demonstrating that acupuncture is a safe and effective medical technique, acupuncture devices must be limited to investigational or research use and labeled accordingly.

94P-0443

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Devices that were in investigational status before the enactment of the Medical Device Amendments of 1976 are not considered to have been in commercial distribution for purposes of section 513 of the Act.

After review of the information submitted in the petitions and its own literature search of safety information, FDA has determined that acupuncture needles intended for use in the practice of acupuncture by qualified practitioners as determined by the States could safely be reclassified from class III to class II with the implementation of special controls.

The special controls are compliance with 1) labeling provisions for single use only and the prescription statement in 21 CFR 801.109 (restriction to use by or on the order of qualified practitioners as determined by the States), 2) device material biocompatibility, and 3) device sterility. FDA believes that information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any hazards, contraindications, side effects and precautions are commonly known to qualified practitioners of acupuncture. Therefore, pursuant to section 801.109(c), such indications do not need to be on the dispensing packaging but sale must be clearly restricted to qualified practitioners of acupuncture. Guidance on the type of information needed to support biocompatibility and sterility can be found in the existing General Hospital Branch Guidance on the Content of Premarket [510(k)] Submissions for Hypodermic Single Lumen Needles, April 1993. A copy of this guidance is enclosed.

FDA's decision is also in keeping with but not dependent upon the recommendation of the Anesthesiology Devices Advisory Panel, published in the Federal Register of November 2, 1979 (44 FR 63299) that acupuncture needles be classified in class II. The supplemental data sheet completed by that panel, dated November 30, 1976, listed sepsis, excessive trauma and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use.

Therefore, FDA, for the reasons set forth in this letter, is ordering the reclassification of the generic type of device identified on page 1, from class III to class II. Further, since the reclassification is based upon scientific evidence demonstrating that general controls and the special controls provide a reasonable assurance of safety and effectiveness, the labeling requirements of the 1973 Federal Register document no longer apply to acupuncture needles intended for use in the practice of acupuncture by qualified practitioners. However, before acupuncture needles can be legally marketed, they must be the subject of a cleared premarket notification [510(k)] submission.

The clinical studies and safety information included in support of these petitions report few risks to health associated with the use of acupuncture needles and those that are reported have been clearly identified, documented and characterized. FDA's own search of the literature supports this finding. The risk to health most frequently found was infection. FDA believes that this risk to health is adequately addressed by the labeling requirements (for single use only and the prescription statement) and the biocompatibility and sterility performance requirements. The risks to health of excessive trauma and perforation of blood vessels and organs are also addressed by the prescription use requirement, restricting use to qualified practitioners of acupuncture as determined by the States.

The clinical studies and preclinical animal studies included in the petitions constitute valid scientific evidence in support of the clinical effectiveness of acupuncture needles for the performance of acupuncture treatment. However reference to a specific disease, condition, or therapeutic benefit requires additional valid scientific evidence in the form of well-controlled prospective clinical studies.

Accordingly, FDA is reclassifying acupuncture needles intended for the practice of acupuncture into class II (special controls) with the special controls identified as labeling, biocompatibility, and sterility requirements. A notice will be published in the Federal Register announcing the Agency's reclassification order.

Copies of this order and supporting documentation will be on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-23, 1220 Parklawn Drive, Rockville, MD 20857 and are available for inspection between 9 a.m.and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Timothy A. Ulatowski at (301) 443-8879. Please convey this information to your membership. Thank you for your cooperation throughout this review process.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2013]
[CITE: 21CFR801.109]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 801 -- LABELING

Subpart D--Exemptions From Adequate Directions for Use

Sec. 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented:*Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a

proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder--piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

In conformance with the requirements for prescription devices set out in 21 Code of Federal Regulations (CFR) 801.109, acupuncture needles are to be sold only to "*qualified practitioners of acupuncture* as determined by the States" (emphasis added). Accordingly, labeling on the package from which acupuncture needles are to be dispensed bears the prescription statement "Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States" (emphasis added).

SAMPLE LABELS

(1) AcuMaster-brand acupuncture needles (Manufactured in China)

The prescription labeling on a dispensing package of AcuMaster-brand acupuncture needles states:

> CAUTION FOR U.S. ONLY: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.
>
> (Emphasis added.)

(2) Carbo-brand acupuncture needles (Manufactured in China)

The prescription labeling on a dispensing package of Carbo-brand acupuncture needles states:

> Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.
>
> (Emphasis added.)

(3) DBC-brand acupuncture needles (Manufactured in Korea)

The prescription labeling on a dispensing package of DBC-brand acupuncture needles states:

> Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.
>
> (Emphasis added.)

(4) Dongbang-brand acupuncture needles (Manufactured in Korea)

The prescription labeling on a dispensing package of Dongbang-brand acupuncture needles states:

> Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.
>
> (Emphasis added.)

(5) Seirin-brand acupuncture needles (Manufactured in Japan)

The prescription labeling on a dispensing package of Seirin-brand acupuncture needles states:

> Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.
>
> (Emphasis added.)