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BAH

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Bonn, 26.07.2001 An/Hu
Hu/allgkorr/Food and Drug

Medical Devices; Global Harmonisation Task Force; Study Group 1; Working Draft "Medical Devices Classification"

Dear Ladies and Gentlemen,

BAH is the German Medicines Manufacturers Association and has more than 300 member companies, mostly small and medium sized drug enterprises. About 50 of them also produce medical devices close to medicinal products, like irrigation solutions, dental filling materials or mud-bathes.

In Federal Register Vol. 66, No. 95 of May 16, 2001 p. 27150 f. FDA, Department of Health and Human Services, informed about the Draft document entitled "Medical Devices Classification", that Study Group 1 of the Global Harmonisation Task Force (GHTF) has prepared on premarked regulation of medical devices.

We have the following comment concerning chapter 8 "Classification Rules" of this document:
No. 8 of this chapter lays down, that all active and non-active implantable devices...are in Class C with some exceptions.
Within these exceptions we are missing implantable devices intended to be placed in the teeth, in which case they are in Class B, not only those implantable devices, which undergo chemical change.

According to the text of the current GHTF-draft document implantable devices being placed in the teeth (e.g. dental filling materials or inlays) belong to Class C independently whether they undergo a chemical change (in which case they fall under the exception of the last indent of No. 8) or not.

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We apply, that no. 8 of the classification rule of the draft GHTF-document will be harmonised with the correspondent European classification rules (see Annex IX rule 8 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ. L 196, 12.07.93, p. 1). This already existing European-wide legislation didn't reveal any safety problems so far. Thus, the wording of no. 8 of the Classification Rules of the draft GHTF document should read (amendments in bold letter):

"8. All active and non-active implantable devices, ...are in Class C unless they are intended:

- **to be placed in the teeth, in which case they are in Class B,**
- to be used in direct contact with the heart,..."
- ...
- ...
- or to undergo chemical change in the body, except if the device are placed in the teeth,...are in Class D."

And as the decision tree at the end of the GHTF Draft document contains within rule 8 as first exception "Placed in the teeth; Class B" we assume that the missing indent in chapter 8 rule 8 is an editorial mistake. But nevertheless, it should be corrected.

Yours sincerely,

Dr. Ehrhard Anhalt

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