Guidelines for Dental Issues

March 31, 1999

Listed below are some examples of recent inquiries of antimicrobial dental uses we have received. Included with each example is the corresponding jurisdiction, EPA or FDA.

1. Sterilization of dental tools/instruments classified as a critical or semi-critical piece of equipment - FDA In order for a product to be regulated exclusively by FDA, two criteria must be met:

    a. A sterilization claim must be made,
    b. The product must contain directions for use on a critical or semi-critical device.

2. Addition of an antimicrobial substance to a dental line on a continuous basis to keep the line clean of bacteria - FDA (510(K)), EPA registration of antimicrobial product. Note that EPA will perform its own risk assessment and can register the use prior to the completion of the FDA 510K process. If we do register the use before FDA completes its review, then the registration notice/amendment acceptance letter needs to contain a statement informing the registrant that appropriate approval is needed from FDA before marketing the dental use.

3. Impregnation of a substance into a dental line for bacterial control - FDA (510(k) required)

    EPA registration of the antimicrobial product. Again, EPA will perform its own risk assessment and can register the use prior to the completion of the FDA 510K process. The acceptance letter needs to contain a statement informing the registrant that appropriate approval is needed from FDA before marketing the dental use.

4. Disinfection of dental pumice used to polish dental appliances (false teeth, bridges, partials, etc.) - EPA

5. Antimicrobial denture cleansers (Efferdent et al) - EPA

6. Disinfection of surfaces of dental machines - EPA/FDA The same process as described in # 2 and 3 above applies here also.

7. Addition of an antimicrobial substance to a dental line to clean the dental line (most likely a biofilm claim) followed by a rinse - EPA. Note that a claim for control of biofilm for a dental use will require the submission of efficacy data and there are no efficacy methods avialable for developing this data. Therefore, a protocol must be submitted which will be subjected to a full range of validation and peer review. Other claims for biofilm control will be evaluated on a case-by-case basis. Some uses such as cooling towers will not require efficacy data.