



Bayerisches Staatsministerium für
Umwelt und Gesundheit



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Ihre Nachricht

Unser Zeichen
E1b-A0082.0-2012/16-3

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München
19.04.2012

**Konsultationsverfahren (Sanco.ddg1.d.6(2012)73176)
Delegated act on the principles and guidelines of good manufacturing practice for active substances in medicinal products for human use; concept paper submitted for public consultation**

Sehr geehrte Damen und Herren,

Im Rahmen des o.g. Konsultationsverfahren nimmt das **Bayerische Staatsministerium für Umwelt und Gesundheit** wie folgt Stellung:

Consultation item No. 1: Do you agree with this appraisal and approach? Please comment.

Answer: We agree with the extension of the Directive on GMP for medicinal products to active substances.

Consultation item No. 2: Are there other aspects which should be considered? Please comment.

Answer: We agree with the adaption of regulatory requirements of Directive 2003/94/EC to active substances and with the provisions in Directive 2003/94/EC that would not apply to active substances.

Consultation item No. 3: Do you consider this list complete? Please comment.

Answer: We agree with the Provisions in Directive 2003/94/EC that would need to be amended and have no further issues to add.

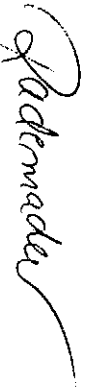
Consultation item No. 4: Do you agree with this specific point? Do you consider that other provisions specific to active substances should be added?

Answer: We agree with an obligation placed on the manufacturer of the active substance to make ensure that the starting material is sourced from the premises claimed by the manufacturer of the starting material.

Consultation item No. 5: Please comment on section 3. Please raise any other issues or add any other comments you wish to make which have not been addressed in the consultation items set out above.

Answer: We agree with the date of transposition of the delegated act and have no further issues.

Mit freundlichen Grüßen



Dr. Elisabeth Rademacher