



The European Agency for the Evaluation of Medicinal Products
Directorate

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Public statement

EU – US FDA bilateral meeting

The European Commission, the European Agency for the Evaluation of Medicinal Products (EMA) and the US Food and Drug Administration (FDA) announced on 12 September 2003 that they have concluded a confidentiality agreement.

The exchange of letters took place as part of the regular cycle of EU-FDA bilateral meetings that have taken place since 1989. The meeting, at the EMA in London on 12 September 2003, addressed a number of other topics including the implementation of the agreement and areas for future cooperation between the two agencies.

The agreement will allow the EMA, FDA and European Commission to exchange information as part of their regulatory processes, both pre- and post-approval. The types of information covered include regulatory issues, scientific advice, orphan drug designation, inspection reports, marketing approvals and post-authorisation surveillance information.

The agreement builds on the close cooperation over the years between European and US pharmaceutical regulators. Its primary aim is to strengthen communication between these public authorities and reinforce public health promotion and protection.

The agreement will be implemented in a step-wise manner. One priority area for the two agencies that is likely to have immediate benefit from this agreement is the possibility of parallel scientific advice from both regulators to companies as they develop new medicines.

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NOTES

1. Information on the work of the FDA is available at <http://www.fda.gov>, of the European Commission Pharmaceuticals Unit at <http://pharmacos.eudra.org> and of the EMA at <http://www.ema.eu.int>
2. The letters are available on the EMA web site

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