Notification Number: 2001/16/F

Draft Order on the content of the file accompanying the declaration laid down in Article L. 5138-1 of the Public Health Code and in the annual summary statement of this declaration

Date received : 17/01/2001

End of Standstill : Closed

Postponement : Yes

Message

Departement of Trade and Industry - Stan dards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

EFTA Surveillance Authority
Ms Solveig Georgsdottir

ELOT
Mr E. Melagrakis

European Free Trade Association
Ms Anne-Lise Bakke-D'Aloya

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium
Fru Kerstin Carlsson

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financiën - Belastingsdie nst - Douane / CDIU
De Heer IJ.G. van der Heiden

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
.

Représentation Permanente du Royaume-Uni
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Message 002

Communication from the Commission - SG(2001) D/50123
Directive 98/34/EC
Translation of the message 001
Notification: 2001/16/F

(MSG: 200100123.EN)

1. Structured Information Line
MSG 002 IND 2001 0016 F EN 18-04-2001 17-01-2001 F NOTIF 18-04-2001

2. Member State
FRANCE

3. Department Responsible
Secrétariat général du Comité interministériel
pour les Questions de Coopération Economique
Européenne
2, Bd Diderot 75012 Paris

Délégué interministériel aux Normes
64-70 allée de Bercy TELEDOC 811
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3. Originating Department
Service responsable de l'élaboration du texte :
Ministère de l'Emploi et de la Solidarité
Direction générale de la santé
Sous-direction de la politique des produits de santé
Madame Hélène Sainte-Marie
8, avenue de Ségur
75350 Paris 07 SP

4. Notification Number
2001/16/F - COOP

5. Title
Draft Order on the content of the file accompanying the declaration laid down in Article L. 5138-1 of the Public Health Code and in the annual summary statement of this declaration

6. Products Concerned
Starting materials of medicinal products

7. Notification Under Another Act
This Notification is made pursuant to Article 8 of Directive 98/34/EC of the European Parliament and of the

Council of 22 June 1998, amended, laying down a procedure for the provision of information in the field of technical standards and regulations.

8. Main Content
This draft Order, made by the Minister responsible for Health at the proposal of the Director-General of the French Agency for the Safety of Health Products, lays down the content of the explanatory file accompanying the declaration. This explanatory file includes administrative information regarding the establishment where the manufacture, import or transport of starting materials of medicinal products is carried out, as well as technical information including in particular the list of manufactured, imported or transported starting materials of medicinal products and a description of the operations carried out and the procedures used.

Moreover, this draft Order lays down the methods for informing the Director-General of the French Agency for the safety of Health Products, of the annual summary statement of amendments concerning the explanatory file.

9. Brief Statement of Grounds
Both the establishment's declaration and explanatory file must allow a register to be compiled of the establishments and allow their activities to be known in order to facilitate and prepare routine inspections, inspections following details of accidents or inspections carried out prior to the issue of a certificate of conformity with good practices. To this end, administrative and technical information is required from the establishments. This information must also enable the kinds of activities carried out to be defined in both qualitative and quantitative terms.

Knowledge of establishments which manufacture, import and transport starting materials of medicinal products will enable greater knowledge of the circulation of products in order, if necessary, to be able to ensure the traceability of the active ingredients and certain excipients in the interests of public health.

10. Reference Documents - Basic Texts
- Proposal for a Directive of the European Parliament and of the Council on good manufacturing practice for starting materials of medicinal products and inspection of manufacturers;

- Public Health Code, in particular Articles L.5138-1, L.5138-2, L.5138-3, L. 5311-1, R. 5115-4 and R. 5171;

- Penal Code, in particular Articles 121-2, 131-38, 132-11 and R. 610-1.

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
No

14. Fiscal measures

No

David O'Sullivan
Secretary-General
European Commission