ORDER
on approval of Norms on the enforcement of certain provisions of Regulation No. 141/2000/EC on orphan medicinal products

Taking into account:

- provisions of Law No. 95/2006 on healthcare reform, as amended;
- Government Ordinance No. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as amended,

based on Government Decision No. 862/2006 on organisation and functioning of the Ministry of Public Health,

on seeing the Approval Report of the Pharmaceutical Sector No. E.N. 8501 of 29 December 2006,

the Minister of Public Health hereby issues the following order:

Article 1. – The Norms on the enforcement of certain provisions of Regulation No. 141/2000/EC on orphan medicinal products, according to the Annex which is integral part of the present order, are approved.

Article 2. – On this order coming into force, the Order of the Minister of public health No. 1.063/2003 shall be repealed on approval of the Norms on the establishment of the criteria attesting a medicinal product as an orphan medicinal product and its Market Authorisation variant, published in the Official Gazette of Romania, Part I, No. 874 of 9 December 2003.

Article 3. – The present order shall be published in the Official Gazette of Romania, Part I.

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The present order settles the frame for the enforcement of European Parliament and Council Regulation No. 141/2000/EC of 16 December 1999 concerning orphan medicinal products (OJ L 18 of 22 January 2000, p. 1-5).

Minister of Public Health
Gheorghe Eugen Nicolăescu

Bucharest, 29 December 2006.
No. 1807.

ANNEX

NORMS
on the enforcement of certain provisions of Regulation No. 141/2000/EC concerning orphan medicinal products

Article 1. – Romania's representative in the Committee, as mentioned under Article 4 (3) of Regulation No. 141/2000/EC concerning orphan medicinal products, further called *Regulation*, is proposed by the President of the National Medicines Agency and submitted for approval to the NMA Administration Council.

Article 2. –If noncompliant with Article 8 (1) from the Regulation, the application approved by the National Medicines Agency is ineffective.

Article 3. – The National Medicines Agency is the national authority capable of gathering the information mentioned under Article 8 (2) and the upgrade of information under Article 9 (2) from the Regulation.