

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health)  
NOTIFICATION

New Delhi, the 4<sup>th</sup> April, 2002.

G.S.R. 250(E).- Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), at page 2 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) dated the 24<sup>th</sup> August, 2001, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), Number G.S.R. 602 (E), dated the 24<sup>th</sup> August, 2001 inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 25.8.2001;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (2<sup>nd</sup> Amendment) Rules, 2002.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, in Schedule P, under the heading 'ANTIBIOTICS', against Sl. No. 75 and the entries relating thereto, the following shall be substituted, namely:-

1	2	3	4
"75	Rifampicin Capsules	36	"

[No. X-11014 / 5 / 2001 – DMS & PFA]

DEEPAK GUPTA, Jt. Secy.

Foot note.- The principal rules were published in the Official Gazette vide notification number F.28-10/45-H(1), dated the 21<sup>st</sup> December, 1945 and last amended vide G.S.R. 909(E), dated 20.12.2001.

The Drugs and Cosmetics Rules, 1945, as amended upto the 1<sup>st</sup> May, 1979 are contained in the publication of the Ministry of Health and Family Welfare (Department of Health) containing the Drugs and Cosmetics Act, 1940 (P DGHS-61).

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health)  
NOTIFICATION

New Delhi, the 4<sup>th</sup> April, 2002.

G.S.R. 249(E).- Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in part -II, Section 3, Sub-section (i), of the Gazette of India, Extraordinary, dated the 9<sup>th</sup> November 2001, vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R 841 (E), dated the 9<sup>th</sup> November 2001, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette Notification were made available to the public on 10.11.2001;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

And whereas the Central Government is of the opinion that circumstances have arisen which render it necessary to make rules without consulting Drugs Technical Advisory Board;

And whereas the Central Government proposes to consult the Drugs Technical Advisory Board within six months of making these rules;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. 1. (1) These rules may be called the Drugs and Cosmetics (1<sup>st</sup> Amendment ) Rules, 2002.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. 2. In the Drugs and Cosmetics Rules, 1945, in rule 3A, -
  - (i) (i) in sub-rule (1A), after item (b), the following item shall be inserted, namely:-  
“(c) The national Institute of Biologicals, NOIDA”,
  - (ii) (ii) after sub-rule (7), the following sub-rule shall be inserted, namely:-

“(8) The functions of the Laboratory in respect of Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus shall be carried out at the National Institute of Biologicals, NOIDA and the functions of the Director in respect of the said drugs shall be exercised by the Director of the said laboratory.”

[No. X-11014 /11 / 2001 – DMS & PFA]

DEEPAK GUPTA, Jt. Secy.

Foot note.- The principal rules were published in the Official Gazette vide notification number F.28-10/45-H(1), dated the 21<sup>st</sup> December, 1945 and last amended vide G.S.R. 909(E), dated 20.12.2001.

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health)  
NOTIFICATION

New Delhi, the 25<sup>th</sup> June, 2002.

G.S.R. 447(E).- Whereas a draft of certain rules further to amend the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 was published as required by Section 3 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (21 of 1954), at page 2 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) dated the 6<sup>th</sup> February, 2002, under the notification of the government of India in the Ministry of Health and Family Welfare (Department of Health), Number GSR 85(E), dated the 6<sup>th</sup> February, 2002 inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Section 3 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955, namely:-

1. (1) These rules may be called the Drugs and Magic Remedies (Objectionable Advertisements) Amendment Rules, 2002.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955, for Schedule, the following Schedule shall be substituted, namely:-

“SCHEDULE”

(See Rule 6)

1. Asthma
2. AIDS”

[No. X-11035/26/2002-DMS & PFA]

DEEPAK GUPTA. Jt. Secy.

Foot Note: The Principal rules were published in the Official Gazette vide Notification No. SRO 512 dated 26<sup>th</sup> February, 1955 and last amended vide GSR 442(E) dated 1<sup>st</sup> June, 1982.

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health)  
NOTIFICATION

New Delhi, the 1<sup>st</sup> May, 2002.

G.S.R. 311(E).- Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), at pages 3 and 4 in Part II, Section 3, Sub-section (i), of the Gazette of India, Extraordinary, dated the 19<sup>th</sup> October, 2001, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 785 (E), dated the 19<sup>th</sup> October, 2001 inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 20<sup>th</sup> October, 2001.

And whereas objections or suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. 1. (1) These rules may be called the Drugs and Cosmetics (3<sup>rd</sup> Amendment) Rules, 2002.  
(2) (2) They shall come into force on the date of their publication in the Official Gazette.
2. 2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 69, after sub-rule (5), the following sub-rule shall be inserted, namely:-

“(6) Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing, in favour of the applicant, from the licensing authority as defined in clause (b) of rule 21.”

3. 3. In rule 71 of the said rules, in sub-rule (6), after clause (iv), the following clause shall be inserted, namely:-

“(v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in rule 122-E, from the licensing authority as defined in clause (b) of rule 21.”

4. 4. In rule 75 of the said rules, in sub-rule (5), the following sub-rule shall be inserted, namely:-

“(6) Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing, in favour of the applicant, from the licensing authority as defined in clause (b) of rule 21.”

5. 5. In rule 76 of the said rules, in sub-rule (7), after clause (iv), the following clause shall be inserted, namely:-

“(v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in rule 122-E, from the licensing authority as defined in clause (b) of rule 21.”

(No.X-11014/4/2000-DMS&PFA)  
DEEPAK GUPTA, Jt. Secy.

Foot note:- The Drugs and Cosmetics Rules, 1945, as amended upto 1.5.1979 are contained in the publication of the Ministry of Health and Family Welfare (Department of Health) containing the Drugs and Cosmetics Act, 1940 and the Rules (PDGHS-61) and last amended vide G.S.R. 250 (E), dated 4.4.2002.