File No 12-[illegible]/13-DC (Pt-54)
Directorate General of Health Services
Office of Drugs Controller General (India)
(New Drug Division)

औषधि नियंत्रक (राज.) जयपुर
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5261

FDA Bhawan,
Kotla Road, New Delhi
Dated [illegible] 2013

To
State Drug Controllers [illegible]

Subject: [illegible] of Rule 97 of Drugs and Cosmetics Rules 1945 regarding withdrawal period.

[illegible]

Pl See

Please refer to the above mentioned rule (copy enclosed) which requires that the container of a medicine for treatment of food producing animals shall be labelled with the withdrawal period of [illegible] for the species on which it is intended to be used:

Provided that if the specific withdrawal period has not been validated, the withdrawal period shall not be less than seven days for eggs or milk, twenty eight days for meat from poultry and mammals including fat and offal, five hundred degree days for fish meat.

You are requested to ensure that the above requirement under Drugs and Cosmetics Rules is strictly implemented by the manufacturers of veterinary medicines used for food producing animals so that the food stuffs produced from animals do not contain residues of drugs in quantities in excess of the maximum residue limits laid down.

Yours faithfully

(Dr. G. N. Singh)
Drugs Controller General (I)

अति शीघ्र
DC
May circulate for compliance - All vet. medicines manufacturers of State, including website, RPMA [illegible] of R-97(3A) please [illegible]
19/9/2013

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN, TILAK MARG JAIPUR

No.DC/D-1/General File/2013/ 409 **Dated:- 16.09.2013**

Copy forwarded to following for necessary action:-

01- All Veterinary Medicines Manufacturers, Rajasthan State.
02-Rajasthan Pharmaceutical Manufacturer's Association, Sp-2, 22 Godam Industrial Estate, Jaipur for needful action.
03- Formulation Committee (Sh. Manoj Dheer) Hqrs.
04. I/c, Server Room to upload the letter on Departmental website. Encl:- As above

13/9/2013
(V.K. Dhal)
Drugs Controller
Rajasthan Jaipur

(a) if it contains a substance specified in Schedule G, be labelled with the words 'Caution: it is dangerous to take this preparation except under medical supervision'—conspicuously printed and surrounded by a line within which there shall be no other words;

(b) if it contains a substance specified in Schedule H be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and be also labelled with the following words:—

'Schedule H drug—Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only';

(c) if it contains a substance specified in Schedule H and comes within the purview of the [Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985)] be labelled with the symbols NRx which shall be in red and conspicuously displayed on the left top corner of the label, and be also labelled with the following words:—

'Schedule H drug—Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only';

(d) if it contains a substance specified in Schedule X, be labelled with the symbol XRx which shall be in red conspicuously displayed on the left top corner of the label, and be also labelled with the following words:—

'Schedule X drug—Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only';

(2) The container of an embrocation, liniment, lotion, [2][ointment, antiseptic eam,] liquid antiseptic or other liquid medicine for external application shall be belled with the words in capital 'For External use only'.]

[3][(3) The container of a medicine made up ready only for treatment of an imal shall be labelled conspicuously with the words 'Not for human use; for imal treatment only', and shall bear a symbol depicting the head of a domestic nimal.]

[4][(3A) The container of a medicine for treatment of food producing animals hall be labelled with the withdrawal period of the drug for the species on which t is intended to be used:

Provided that if the specific withdrawal period has not been validated, the withdrawal period shall not be less than seven days for eggs or milk, twenty eight days for meat from poultry and mammals including fat and offal, five hundred degree days for fish meat.

Explanation.—For the purpose of this rule, the withdrawal period is the period of interval between the last administration of a veterinary medicine to animals under the normal conditions of use and the production of food stuff

1. Subs. by G.S.R. 282(E), dated 16th July, 1996 (w.e.f. 16-7-1996), as corrected by G.S.R. 241(E), dated 15th April, 1998.
2. Ins. by G.S.R. 850(E), dated 7th December, 1994 (w.e.f. 7-12-1994).
3. Subs. by Notification No. F. 1-6/62-D (S.O. 2889), dated 2nd July, 1969 (w.e.f. 19-7-1969).
4. Ins. by G.S.R. 128(E), dated 17th January, 2012 (w.e.f. 17-1-2012).

from such animals to ensure that food stuffs do not contain residues in quantities in excess of the maximum residue limits laid down.]

[1][(4) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methylated spirit, indicate this fact on the label and be labelled with the words—

"FOR EXTERNAL USE ONLY".]

[2][(5) Substances specified in Schedule X in bulk form shall bear a label wherein the symbol as specified in sub-rule (1) shall be given conspicuously in red letters.]

[3][***]

[4][102. **Sterile Surgical Ligature and Suture.**—Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile, shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words "Non-sterile surgical ligature (suture)—not to be used for operations upon the human body unless efficiently sterilized".]

103. [5][***]

(2) The name and address of the manufacturer shall be printed on the label of the container of a patent or proprietary medicine.

[6][(3) The true formula or list of the ingredients shall be printed or written in indelible ink on the outer label of every package containing patent or proprietary medicine.]

[7][**104. Use of letters I.P., etc.**—The letters 'I.P.' and recognised abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the rules.]

[8][**104A. Prohibition against altering inscriptions on containers, labels or wrappers of drug.**—No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug:

Provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the licensing authority.]

[9][**105. Packing of drugs.**—(1) The pack sizes of drugs meant for retail sale shall be as prescribed in Schedule P1 to these rules.

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1. Sub-rule (4) omitted and sub-rule (5) renumbered as sub-rule (4) by G.S.R. 462(E), dated 22nd June, 1982 (w.e.f. 22-6-1982).
2. Ins. by G.S.R. 462(E), dated 22nd June, 1982 (w.e.f. 22-6-1982).
3. Rules 98 to 101 omitted by G.S.R. 462(E), dated 22nd June, 1982 (w.e.f. 22-6-1982).
4. Subs. by Notification No. F. 1-3/51-D.S., dated 15th October, 1954.
5. Sub-rule (1) omitted by Notification No. F. 1-16/57-D (S.O. 2136), dated 15th June, 1957.
6. Subs. by Notification No. F-1-16/57-D (S.R.O. 2136), dated 15th June, 1957.
7. Subs. by G.S.R. 19, dated 15th December, 1977 (w.e.f. 7-1-1978).
8. Ins. by G.S.R. 1242, dated 17th September, 1979 (w.e.f. 6-10-1979).
9. Subs. by G.S.R. 796(E), dated 1st October, 1992 (w.e.f. 1-10-1993).