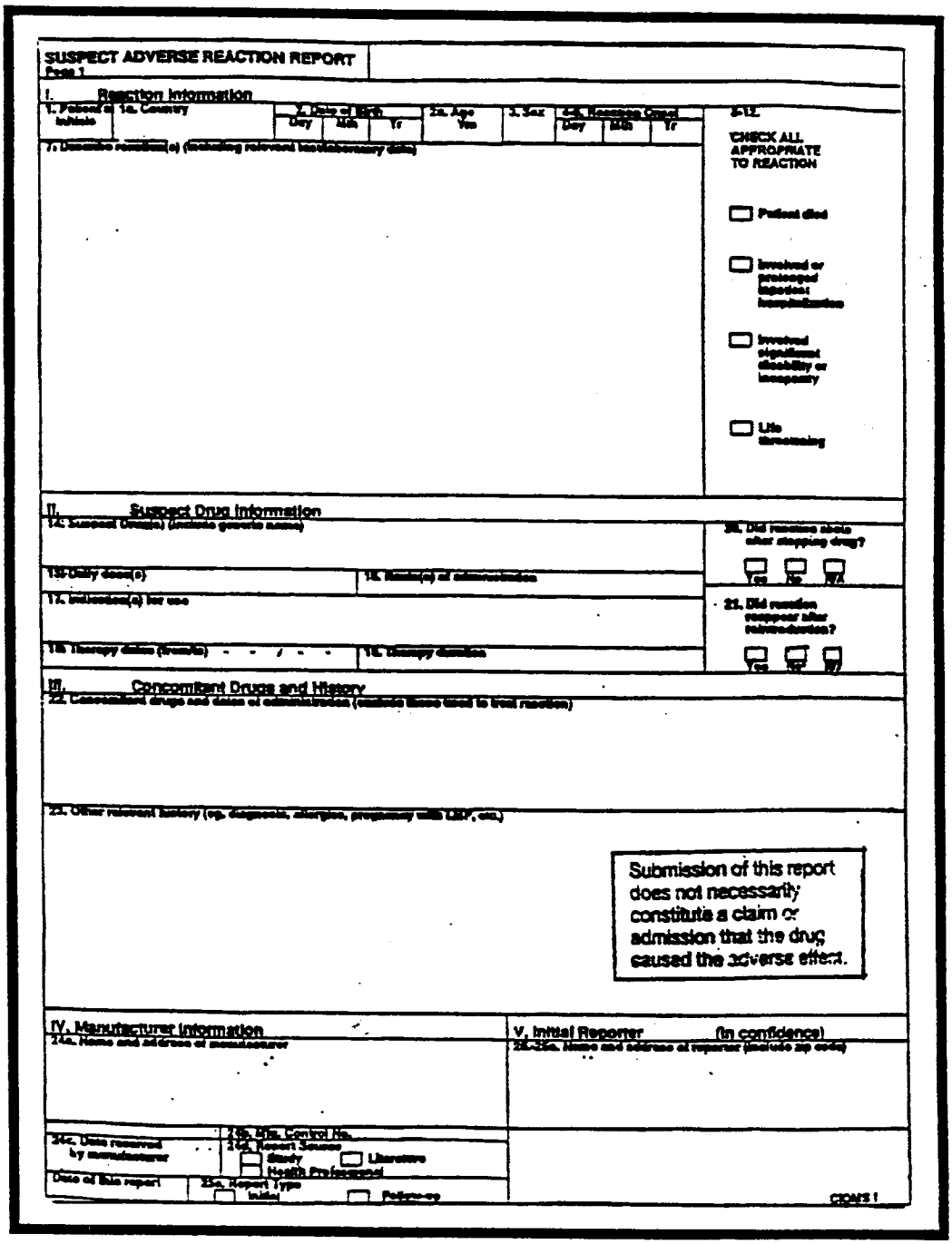

SUSPECT ADVERSE REACTION REPORT

Page 1

I. Reaction Information

1. Patient (initials) | 1a. Country | 2. Date of Birth (Day / Mth / Yr) | 2a. Age (Yrs) | 3. Sex | 4. Reaction Onset (Day / Mth / Yr)

7. Describe reaction(s) (including relevant tests/laboratory data)

5-12. CHECK ALL APPROPRIATE TO REACTION

- Patient died
- Involved or prolonged inpatient hospitalization
- Involved significant disability or incapacity
- Life threatening

II. Suspect Drug Information

13. Suspect Drug(s) (generic name)

13a. Daily dose(s)

13b. Route(s) of administration

14. Indication(s) for use

15. Therapy dates (from/to)

16. Therapy duration

18. Did reaction abate after stopping drug? (Yes / No / N/A)

19. Did reaction reappear after reintroduction? (Yes / No / N/A)

III. Concomitant Drugs and History

22. Concomitant drugs and dates of administration (exclude those used to treat reaction)

23. Other relevant history (eg. diagnostic, allergies, pregnancy with LMP, etc.)

Submission of this report does not necessarily constitute a claim or admission that the drug caused the adverse effect.

IV. Manufacturer Information

24a. Name and address of manufacturer

V. Initial Reporter (In confidence)

25-25a. Name and address of reporter (include zip code)

24b. MFR. Control No.

24c. Date received by manufacturer

24d. Report Source: Study / Literature / Health Professional

Date of this report

25c. Report Type: Initial / Follow-up

CDRH I

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