Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Manufacturing and Product Quality HFM-670
1401 Rockville Pike, Suite 200 South
Rockville, MD 20852-1448

Sending To: Tes Gabten

Fax Number: 827 3843

From: Jay Eltenman

Telephone: (301) 827-3031 FAX: (301) 827-3536

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Remarks: Notes from the series of teleconferences on 10/5 with MHRA and Clinton
Note that pages 4 and 5 appear to be internal discussions

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Thank you.

Jay Eltenman
meeting notes w/
MHRA and Chinon
teleconferences

10/5/2004

- Flu vaccine - GMP issues vaccine
  EMEA revoked license
  Chinon license suspended for 3 months

- apparently not forewarned by MHRA
  "can't release to any market"

MHRA
- EMEA putting report thru now - non-technical -
- suspended - impacts the expert
  ∴ suspended license - suspenses expert
- investigating problem - Liverpool -
  - on site - last week
  ∴ grounds of lack of sterility assurance -!

- appeal right - but cannot do so before 3 months
- won't be able to release any stock

- no assurance that
  - Serratia marcens -

- started in one of monovalent - into trivalent
  - ↳ 4 or 5 batches
  - ↳ end of August - and — recently

formulation
- bioburden - 10^9 org / ml - pre-filtration
- suspended 10 clock this morning

! company aware of the problem since April!

current vaccine is not suitable for us -
- concern strictly on basis of problem - not taking into consideration the benefit of the vaccine and availability -

- meeting with company tomorrow -

- definitive - will not be any FW vaccine

chronology
- temporarily suspend license -

export provision of UK law to be reviewed -

unexpected problems -
may be considered - under
may require add'l conversations

- if impeder the gov't plans - may not release the press release
- ——— - doesn't sound as if there is a channel -
- reg agency to reg agency - fax 3381
- John Reed - Head - MHRA

— situation - - - - has been resolved -

- what has changed? - ANS - in draft press release

- not definitive root cause
- MHRA involved a higher principle -

- what about states and hospitals -
- contact the distributor -

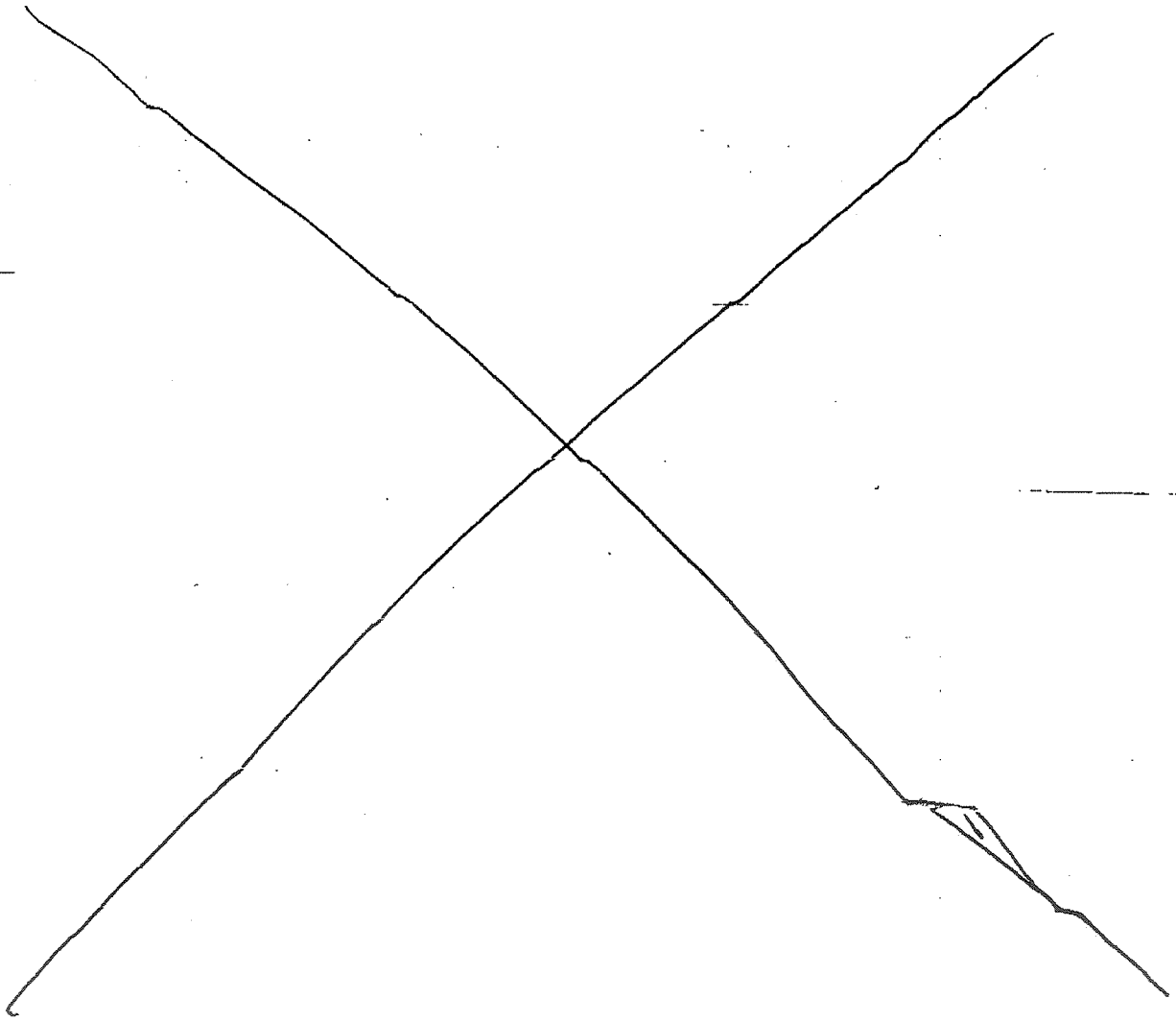
- distributors have not been notified - suspended until press release is issued -

MHRA press release is going out now!

Evans - cont

- contamination in Avg - Date Avg -
- company was focused on isolated - Avg 25
- " " "

↳ we were



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June 2003

→ TPIO = OAI ⇒ VAI
downgraded