Brecher Martin M

From:

Brecher Martin M

Sent:

Thursday, June 22, 2000 11:25 AM

To:

De Vriese Geert; O'Brien Shawn SP; Bache Ricky RA

Subject:

SERM

Folks,

Here are the conclusions of the SERM all of which I supported:

- Diabetes mellitus, diabetic ketoacidosis, non-ketotic hyperosmolar coma, hyperglycemia-Keep issue under review
- 2. Weight gain- Remove qualifying word "limited" from CDS.
- 3. Oculogyric crisis- EPS including oculogyric criis to be studied further and discussed at next SERM.
- 4. Hypertension- No change in CDS
- 5. Hypersensitivity- Add to adverse events section statement that rare cases of hypersensitivity including angioedema have been observed. This change to be implemented in the next 8 weeks.

Martin

