

Four in 10 botox jabs doomed

JAMES CHAPMAN, Daily Mail - 26th June 2003

The company behind the antiwrinkle injection Botox is misleading customers over the risks of the treatment, health authorities claim.

Clinical trials suggest four in ten people who have the jab suffer some sort of side-effect, America's Food and Drug Administration has pointed out.

The FDA said magazine adverts for Botox are misleading and instructed the maker, Allergan, to stop running them.

The adverts falsely identify the injected drug as a cosmetic treatment, fail to reveal important facts about its use and minimise its risks, the regulatory agency said in a letter to the company.

Botulinum therapy has become hugely popular over recent years because it can smooth out crow's feet.

Although lethal in large doses, a purified version of the toxin - the most deadly known to man - can be used to treat conditions where the muscles need to be relaxed. Sir Cliff Richard, Liz Hurley, Lulu, Meg Ryan and Leslie Ash are among those who have had botulinum injections to get rid of facial lines. Sir Cliff complained that they made his eyelids droop.

The FDA's letter accuses Allergan of 'minimising' the risks associated with the treatment.

The company's own information suggests that almost 44 per cent of patients suffer some sort of adverse reaction. These include headaches, nausea, respiratory infection and blepharoptosis - the scientific name for drooping of the eyelids.

Allergan spokesman Christine Cassiano insisted last night that the treatment had been proved safe and effective over many years.

She said that patients receiving 'dummy' jabs of salt water in trials reported almost identical rates of adverse reactions - 41.5 per cent.

The side-effects that had to be recorded, Miss Cassiano added, included reactions as minor as slight redness at the site of the injection.

But the FDA accused Allergan of misleadingly suggesting that the drug is effective for uses such as temporary treatment of frown lines, that go beyond its approved use in the U.S. as a treatment for improving brow furrows.

Steven Masiello, director of the FDA's office of compliance and biologics quality, said in the letter: 'We are very concerned that by continuing to promote Botox Cosmetic in a false and misleading manner these materials are raising significant public health concerns.'

Last year, the FDA issued a similar warning to Allergan, citing print and television adverts that failed to emphasise that Botox was a temporary fix and that suggested it could be used to treat all kinds of wrinkles.

Miss Cassiano said that by far the most common side-effect reported by patients in trials was a temporary headache, whether they had Botox or a dummy jab.

However, around one in 30 people having Botox reported drooping eyelids, compared with none who had the placebo.

'In most instances this disappears, on average within three to four weeks,' she added. 'The benefit-we have seen with Botox has been tremendous. When you look at side-effects that may occur, they are relatively rare.'

'There was only two per cent difference in the rate of side-effects between those patients that received placebo and those that had Botox. It's really very small.'

Nick Percival, a consultant plastic surgeon who has treated hundreds of patients with Botox at the Renaissance Clinic in London, said: 'In my experience, complications are relatively uncommon.'

'I think it's a safe and effective treatment. We all recognise that the drooping of the eyelid can happen - it's a recognised sideeffect. Fortunately, I have never had it happen.'